

# EXHIBIT B

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<div>Page 1</div> <div>UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA</div> <div>-----</div> <div>In Re: Bair Hugger Forced Air Warming Products Liability Litigation</div> <div>This Document Relates To: All Actions MDL No. 15-2666 (JNE/FLM)</div> <div>-----</div> <div>DEPOSITION OF JONATHAN BORAK VOLUME I, PAGES 1 - 251 JULY 20, 2017</div> <div>(The following is the deposition of JONATHAN BORAK, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulevard, Hartford, Connecticut, commencing at approximately 8:09 o'clock a.m., July 20, 2017.)</div>	<div>Page 3</div> <div>INDEX</div> <table><thead><tr><th>EXHIBITS</th><th>DESCRIPTION</th><th>PAGE MARKED</th></tr></thead><tbody><tr><td>Ex 1</td><td>Expert report of Jonathan Borak</td><td></td></tr><tr><td></td><td>Borak</td><td>7</td></tr><tr><td>2</td><td>Borak curriculum vitae</td><td>8</td></tr><tr><td>3</td><td>Jonathan Borak &amp; Company website download</td><td>39</td></tr><tr><td>4</td><td>Article, Mortality Disparities in Appalachia, by Borak, et al</td><td>46</td></tr><tr><td>5</td><td>E-mail sent September 06, 2002</td><td>54</td></tr><tr><td>6</td><td>Exhibit B to Borak's expert report</td><td>61</td></tr><tr><td>7</td><td>Kurz deposition excerpt, January 12, 2017</td><td>76</td></tr><tr><td>8</td><td>E-mail, 3M00580475</td><td>90</td></tr><tr><td>9</td><td>510(k) Summary of Safety &amp; Effectiveness, January 10, 1996, 3MBH00047382-3</td><td>94</td></tr><tr><td>10</td><td>E-mail string, 3MBH00024633-4</td><td>113</td></tr><tr><td>11</td><td>E-mail string, 3MBH00544754-5</td><td>119</td></tr><tr><td>12</td><td>E-mail string, 3MBH00132501-2</td><td>124</td></tr><tr><td>13</td><td>E-mail string, 3MBH00130429-32</td><td>126</td></tr><tr><td>14</td><td>E-mail string, 3MBH01330587-92</td><td>128</td></tr><tr><td>15</td><td>Article, Return to theatre following total hip and knee</td><td></td></tr></tbody></table>	EXHIBITS	DESCRIPTION	PAGE MARKED	Ex 1	Expert report of Jonathan Borak			Borak	7	2	Borak curriculum vitae	8	3	Jonathan Borak & Company website download	39	4	Article, Mortality Disparities in Appalachia, by Borak, et al	46	5	E-mail sent September 06, 2002	54	6	Exhibit B to Borak's expert report	61	7	Kurz deposition excerpt, January 12, 2017	76	8	E-mail, 3M00580475	90	9	510(k) Summary of Safety & Effectiveness, January 10, 1996, 3MBH00047382-3	94	10	E-mail string, 3MBH00024633-4	113	11	E-mail string, 3MBH00544754-5	119	12	E-mail string, 3MBH00132501-2	124	13	E-mail string, 3MBH00130429-32	126	14	E-mail string, 3MBH01330587-92	128	15	Article, Return to theatre following total hip and knee	
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<div>Page 2</div> <div>APPEARANCES:</div> <div>On Behalf of the Plaintiffs:</div> <div>Jan M. Conlin</div> <div>CIRESI CONLIN L.L.P.</div> <div>225 South 6th Street, Suite 4600</div> <div>Minneapolis, Minnesota 55402</div> <div>On Behalf of Defendants:</div> <div>Corey L. Gordon</div> <div>BLACKWELL BURKE P.A.</div> <div>431 South Seventh Street, Suite 2500</div> <div>Minneapolis, Minnesota 55415</div> <div>ALSO APPEARING:</div> <div>Ronald M. Huber, Videotechnician</div>	<div>Page 4</div> <div>replacement, before and after the introduction of rivaroxaban, by Jensen, et al 145</div> <div>16 Article in Health Devices, Force-Air Warming and Surgical Site Infections 154</div> <div>17 Article, Wound Complications Following Rivaroxaban Administration, by Jameson, et al 154</div> <div>18 Reed deposition transcript, December 4, 2016 161</div> <div>19 Article, Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis, by Darouiche, et al 170</div> <div>20 Article, Preventing Surgical-Site Infections in Nasal Carriers of Staphylococcus aureus, by Bode, et al 175</div> <div>21 Article, Effects of preoperative warming on the incidence of wound infection after clean surgery: A randomised controlled trial, by Melling, et al 190</div> <div>22 Article, Prophylactic antibiotics</div>																																																			

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1	in elective hip and knee			1	PROCEEDINGS		
2	arthroplasty, by Hickson, et al	193		2	(Witness sworn.)		
3	23 Article, Implementing effective			3	JONATHAN BORAK		
4	SSI surveillance, by Gillson,			4	called as a witness, being first duly sworn,		
5	et al	195		5	was examined and testified as follows:		
6	24 Article, Surveillance of surgical			6	ADVERSE EXAMINATION		
7	site infections in NHS hospitals			7	BY MS. CONLIN:		
8	in England, 2015/16	198		8	Q. Good morning, Professor Borak. Is it --		
9	25 Article, Staphylococcus aureus			9	Do you go by Dr. Borak or Professor Borak?		
10	Screening and Decolonization in			10	<b>A. I -- I guess I'm more comfortable with</b>		
11	Orthopaedic Surgery and Reduction			11	<b>doctor.</b>		
12	of Surgical Site Infections, by			12	Q. Okay.		
13	Chen, et al	203		13	<b>A. I've been a doctor for longer.</b>		
14	26 Centers for Disease Control and			14	Q. Can you spell your last name for the record,		
15	Prevention Guidelines for the			15	please -- or actually your full name.		
16	Prevention of Surgical Site			16	<b>A. Jonathan, J-o-n-a-t-h-a-n, Benjamin,</b>		
17	Infection, 2017	204		17	<b>B-e-n-j-a-m-i-n, Borak, B-o-r-a-k.</b>		
18	27 McGovern deposition excerpt,			18	MS. CONLIN: We can mark that. Do you want		
19	January 4, 2017	215		19	a copy?		
20	28 McGovern deposition excerpt,			20	MR. GORDON: Are you using new numbering		
21	January 5, 2017	230		21	for --		
22	29 Nachtsheim deposition excerpt,			22	MS. CONLIN: Yeah. We'll go with Borak		
23	November 29, 2016	236		23	Exhibit 1.		
24	30 Article, The Environment and			24	(Exhibit 1 was marked for		
25	Disease: Association or			25	identification.)		
Page 6				Page 8			
1	Causation? by Hill	239		1	BY MS. CONLIN:		
2				2	Q. I've handed you a copy of -- or what's been		
3				3	marked as Borak Deposition Exhibit No. 1. Is that		
4	WITNESS EXAMINATION BY PAGE			4	your expert report in this case?		
5	Jonathan Borak Ms. Conlin	7		5	<b>A. That is correct.</b>		
6	Mr. Gordon	240		6	Q. And --		
7	Ms. Conlin	245		7	(Exhibit 2 was marked for		
8	Mr. Gordon	246		8	identification.)		
9	Ms. Conlin	247		9	BY MS. CONLIN:		
10				10	Q. I've handed you, Dr. Borak, what's been		
11				11	marked as Borak Deposition Exhibit No. 2. Is this a		
12				12	copy of your CV?		
13				13	<b>A. I'm sorry, what was your question?</b>		
14				14	Q. Is this a copy of your CV?		
15				15	<b>A. Yeah. There's several more recent</b>		
16				16	<b>publications.</b>		
17				17	Q. Okay. Do you want to, if you know, name		
18				18	those, please.		
19				19	<b>A. The names are long. They both have to do</b>		
20				20	<b>with elemental mercury exposure. They have just been</b>		
21				21	<b>published in the last week in Critical Reviews in</b>		
22				22	<b>Toxicology.</b>		
23				23	Q. Okay. Other than those additions, to the		
24				24	best of your knowledge is Exhibit 2 correct and		
25				25	accurate?		

2 (Pages 5 to 8)

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<p style="text-align: right;">Page 9</p> <p>1       <b>A. I -- I think so, yes.</b></p> <p>2       Q. Okay. I'd like to direct your attention</p> <p>3 back to your expert report in this case dated June</p> <p>4 2nd, 2017 that has been marked as Exhibit 1. I'd like</p> <p>5 to direct your attention, Dr. Borak, to page 23 of</p> <p>6 that.</p> <p>7       Do you have it in front of you, sir?</p> <p>8       <b>A. I do.</b></p> <p>9       Q. Okay. I'd like to direct your attention to</p> <p>10 paragraph 74c --</p> <p>11       <b>A. Yes.</b></p> <p>12       Q. -- where you opine, "The McGovern report</p> <p>13 relied on truncated and incorrectly tabulated data.</p> <p>14 When those irregularities are corrected, the study</p> <p>15 data do not provide evidence that BH" -- Bair</p> <p>16 Hugger -- "is associated with a significant increase</p> <p>17 in SSL."</p> <p>18       That's your opinion; correct?</p> <p>19       <b>A. You read that correctly, yes.</b></p> <p>20       Q. And is that your opinion?</p> <p>21       <b>A. That's my opinion.</b></p> <p>22       Q. Okay. And is that your opinion today?</p> <p>23       <b>A. That is my opinion today.</b></p> <p>24       Q. Okay. Have you reviewed anything since the</p> <p>25 filing of your report on June 2nd of this year?</p>	<p style="text-align: right;">Page 11</p> <p>1       probably the McGovern study because it was a peer-</p> <p>2 reviewed paper, and there was then a discussion of</p> <p>3 some notable paper or papers that had been retracted,</p> <p>4 and I just wondered in my own head how often that</p> <p>5 occurred. I have been in situations as a member of</p> <p>6 editorial boards where it's been necessary to retract</p> <p>7 papers, and I was interested to see whether this was a</p> <p>8 very common phenomenon.</p> <p>9       Q. Okay. Did you undertake that on your own or</p> <p>10 were you requested to do that by lawyers for 3M?</p> <p>11       <b>A. I -- I -- I initiated that on my own.</b></p> <p>12       Q. Okay. And you indicated you read some</p> <p>13 deposition testimony related to Ridgeview. Was that</p> <p>14 by Dr. Augustine?</p> <p>15       <b>A. I -- I did not review deposition testimony</b></p> <p>16 <b>that I'm aware of that was related to Ridgeview</b></p> <p>17 <b>Medical Center, at least I don't remember it as such,</b></p> <p>18 <b>but I looked at a number of documents which were</b></p> <p>19 <b>either marked as exhibits or had Bates numbers on</b></p> <p>20 <b>them.</b></p> <p>21       Q. Who provided those to you?</p> <p>22       <b>A. Mr. Gordon.</b></p> <p>23       MS. CONLIN: Okay. And we'll request an</p> <p>24 updated list of documents reviewed since he offered</p> <p>25 his opinions in this case.</p>
<p style="text-align: right;">Page 10</p> <p>1       <b>A. Yes.</b></p> <p>2       Q. What have you reviewed?</p> <p>3       <b>A. I have reviewed a recent publication by Dr.</b></p> <p>4 <b>Augustine.</b></p> <p>5       Q. Okay.</p> <p>6       <b>A. I have reviewed a number of exhibits from</b></p> <p>7 <b>what I assume to have been depositions or legal</b></p> <p>8 <b>proceedings related to both Augustine and Ridgeview</b></p> <p>9 <b>Medical Center.</b></p> <p>10       Q. Okay. Anything else?</p> <p>11       <b>A. The answer is yes, but you're going to ask</b></p> <p>12 <b>me to be specific. I have looked at a number of</b></p> <p>13 <b>publications related to retractions of peer-reviewed</b></p> <p>14 <b>literature, I have -- I looked at much but not all of</b></p> <p>15 <b>a rough draft of Dr. Holford's deposition, and I have</b></p> <p>16 <b>certainly looked back in my files. Whether in the</b></p> <p>17 <b>course of that I may have looked at additional</b></p> <p>18 <b>articles, it is possible, but they don't come to mind.</b></p> <p>19 <b>I'm not trying to withhold anything.</b></p> <p>20       Q. And what was the purpose for you looking at</p> <p>21 materials related to retraction of peer-reviewed</p> <p>22 articles?</p> <p>23       <b>A. A question arose in my mind based on a</b></p> <p>24 <b>statement made at least once and possibly multiple</b></p> <p>25 <b>times by Dr. Samet, who defended reliance upon</b></p>	<p style="text-align: right;">Page 12</p> <p>1       MR. GORDON: Sure.</p> <p>2       Q. Directing your attention back to paragraph</p> <p>3 74c and your opinion that use of Bair Hugger is not</p> <p>4 associated with an increased risk in SSLs, how do you</p> <p>5 define "associated?"</p> <p>6       <b>A. I think that the operative word there is</b></p> <p>7 <b>"significant," and I was referring to a statistically</b></p> <p>8 <b>significant association.</b></p> <p>9       Q. My question was a little different. How do</p> <p>10 you define "associated" as that word is used in</p> <p>11 paragraph 74c?</p> <p>12       <b>A. I don't think that you can take the word out</b></p> <p>13 <b>of the context. "Associated with a significant</b></p> <p>14 <b>increase" is the statement that I made.</b></p> <p>15       Q. Well you understand that "association" or</p> <p>16 "associated" is an epidemiological term; correct?</p> <p>17       <b>A. It is often used in epidemiology, correct.</b></p> <p>18       Q. Okay. Did you use it in an epidemiologic</p> <p>19 way in connection with your use of the term</p> <p>20 "associated" in paragraph 74c?</p> <p>21       <b>A. Only to the extent that association implies</b></p> <p>22 <b>that there is a relationship -- an apparent</b></p> <p>23 <b>relationship, and the question here was whether there</b></p> <p>24 <b>was a signif -- a relationship indicating a</b></p> <p>25 <b>significant increase.</b></p>

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<p>1 Q. Okay. Would you agree with me that</p> <p>2 "association," as used by epidemiologists, states that</p> <p>3 events are said to be associated when they occur more</p> <p>4 or less frequently together than one would expect by</p> <p>5 chance?</p> <p>6 <b>A. That's probably a -- a reasonable</b></p> <p>7 <b>definition.</b></p> <p>8 Q. Okay. So is it your opinion that use of the</p> <p>9 Bair Hugger is associated with increased infection?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question.</p> <p>12 <b>A. Not necessarily.</b></p> <p>13 Q. Okay. So use of the Bair Hugger and an</p> <p>14 infection would be by chance as opposed to something</p> <p>15 else.</p> <p>16 <b>A. What do you mean "by chance as opposed to</b></p> <p>17 <b>something else?"</b></p> <p>18 Q. Well, do you believe that the Bair Hugger is</p> <p>19 associated with any increased risk of infection?</p> <p>20 <b>A. I am aware of at least one paper, the</b></p> <p>21 <b>McGovern paper, and a subsequent paper which we may</b></p> <p>22 <b>discuss by Augustine, which have alleged that there is</b></p> <p>23 <b>such an association. I'm not aware of any other data</b></p> <p>24 <b>to support that, and I have significant questions</b></p> <p>25 <b>about the validity of both of those papers.</b></p>	<p>1 use of the Bair Hugger is associated with an increased</p> <p>2 risk of infection.</p> <p>3 <b>A. Yes. Excluding those papers, I have seen no</b></p> <p>4 <b>such evidence.</b></p> <p>5 Q. Okay. And when epidemiologists talk about</p> <p>6 events that are said to be associated when they occur</p> <p>7 more or less frequently together than one would expect</p> <p>8 by chance, I would take it that your opinion is that</p> <p>9 the use of a Bair Hugger would have the chance of</p> <p>10 causing an infection along the same lines as a -- a</p> <p>11 Rubber Ducky sitting in the OR; is that right?</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question.</p> <p>14 <b>A. I think there were two elements. One of</b></p> <p>15 <b>them is that there is a chance -- stochastic chance of</b></p> <p>16 <b>something else. The other one is there are other</b></p> <p>17 <b>moving parts in the scenario. And if you want to say</b></p> <p>18 <b>that everything else is held constant, then yes, only</b></p> <p>19 <b>chance.</b></p> <p>20 Q. Okay. So holding everything else constant,</p> <p>21 having a Bair Hugger in use in the OR would increase</p> <p>22 your chance of infection to the same extent that a</p> <p>23 Rubber Ducky sitting in the OR on a table would.</p> <p>24 <b>A. I -- I don't know what risk there is to a</b></p> <p>25 <b>Rubber Ducky, so I can't answer your question.</b></p>
Page 14	Page 16
<p>1 Q. So it's your opinion that the use of the</p> <p>2 Bair Hugger is not associated with an increased risk</p> <p>3 of infection.</p> <p>4 <b>A. I believe it has not been associated outside</b></p> <p>5 <b>of those two papers, which I have concerns about.</b></p> <p>6 Q. Okay. My question was a little different.</p> <p>7 So you --</p> <p>8 Your opinion is that the use of the Bair</p> <p>9 Hugger is not associated with an increased risk of</p> <p>10 infection.</p> <p>11 <b>A. I believe there is insufficient evidence to</b></p> <p>12 <b>make that statement. I believe that it has been</b></p> <p>13 <b>associated in two problematic studies. I don't know</b></p> <p>14 <b>that there is sufficient evidence otherwise.</b></p> <p>15 Q. Right. So you'd agree that it's your</p> <p>16 opinion that the Bair Hugger is not associated with an</p> <p>17 increased risk of infection based on your review of</p> <p>18 the record.</p> <p>19 <b>A. I -- and I am sorry to seem belligerent.</b></p> <p>20 <b>I -- my statement is I don't believe it has been</b></p> <p>21 <b>associated in a meaningful way, and I say that because</b></p> <p>22 <b>there are these two papers, which I would challenge.</b></p> <p>23 Q. Okay. So setting --</p> <p>24 Because you don't believe those papers are</p> <p>25 accurate, you have seen no evidence to find that the</p>	<p>1 Q. Well, do you think that a Rubber Ducky would</p> <p>2 be associated with an increased risk of infection?</p> <p>3 <b>A. I -- I doubt it, but I don't know.</b></p> <p>4 Q. Okay. So assuming that there isn't anything</p> <p>5 unusual about the Rubber Ducky, the use of the Bair</p> <p>6 Hugger -- presence of the Bair Hugger in use in the</p> <p>7 operation -- or in an operating room would be akin to</p> <p>8 having a Rubber Ducky sitting on the table --</p> <p>9 <b>A. I --</b></p> <p>10 Q. -- as it relates to an increased risk of</p> <p>11 infection.</p> <p>12 <b>A. I -- I --</b></p> <p>13 <b>Once again, if you would rephrase your</b></p> <p>14 <b>question in a different way. You keep talking about</b></p> <p>15 <b>this Rubber Ducky, and it's something I don't know</b></p> <p>16 <b>anything about.</b></p> <p>17 Q. Well you've seen the little ducks that float</p> <p>18 around in a bathtub.</p> <p>19 <b>A. Oh, I understand conceptually what you're</b></p> <p>20 <b>speaking about, but in context I have no knowledge at</b></p> <p>21 <b>all. I can't answer the question as you pose it.</b></p> <p>22 Q. Why not?</p> <p>23 <b>A. Because I don't know what the risks are of a</b></p> <p>24 <b>Rubber Ducky, and there may be issues that I haven't</b></p> <p>25 <b>appreciated.</b></p>

4 (Pages 13 to 16)

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<p>1           <b>You might ask Dr. Wenzel, who is an expert</b>  2           <b>in nosocomial infections. He may have experience with</b>  3           <b>Rubber Duckies.</b>  4           Q. Okay. Well in any event, your view is use  5           of the Bair Hugger during a surgical procedure, such  6           as an orthopedic implant, does not increase the risk  7           of infection to a patient; correct?  8           <b>A. No. My opinion is that I have not seen any</b>  9           <b>evidence that it does, outside of two studies which I</b>  10           <b>consider to be problematical.</b>  11           Q. Okay. And because you're saying those  12           studies are problematic, it's your opinion that use of  13           the Bair Hugger does not increase the risk of  14           infection for a patient undergoing arthroplastic  15           surgery.  16           <b>A. I am not aware of any evidence that it does</b>  17           <b>so.</b>  18           Q. Okay. Do you consider yourself an  19           epidemiologist?  20           <b>A. I'm a professor of epidemiology. I do a lot</b>  21           <b>of work at the interface step of epidemiology and</b>  22           <b>toxicology and other such related things, yes.</b>  23           Q. Okay. So you do hold yourself out as an  24           epidemiologist.  25           <b>A. I am a professor of epidemiology.</b></p>	<p>1           ascertaining whether an event or something causes a  2           risk to the general population?  3           <b>A. I'd certainly do research.</b>  4           Q. Okay. And as part of that study, I take it  5           you would attempt, as an epidemiologist, to look at  6           all the evidence associated with a particular risk of  7           an event to the general population.  8           <b>A. In principle, that sounds right.</b>  9           <b>(Discussion off the stenographic record.)</b>  10           Q. I think you mentioned this, but you're not  11           an expert in infectious disease; correct?  12           <b>A. No, I'm not. Infectious disease is part of</b>  13           <b>internal medicine, but I am not boarded in -- in</b>  14           <b>infectious disease.</b>  15           Q. Do you have any experience in  16           anesthesiology?  17           <b>A. No, not particularly.</b>  18           Q. How about normothermia or hypothermia?  19           <b>A. I have treated both, but I don't consider</b>  20           <b>myself an expert in either.</b>  21           Q. Okay. Do you consider yourself having any  22           expertise in orthopedic surgery?  23           <b>A. I have not done surgery as a professional</b>  24           <b>activity after training.</b>  25           Q. And do you consider yourself a statistician?</p>
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<p>1           Q. Okay. You have a degree in -- well let's  2           back up.  3           Are you making a distinction between saying  4           you are a professor of epidemiology and an  5           epidemiologist?  6           <b>A. I am not a board certified epidemiologist.</b>  7           Q. Okay. And you don't have a degree in  8           epidemiology; correct?  9           <b>A. I do not have a specific degree in</b>  10           <b>epidemiology.</b>  11           Q. Your degree is in internal medicine?  12           <b>A. In medicine.</b>  13           Q. Okay. Do you have any clinical experience  14           in epidemiology?  15           <b>A. I have done epidemiology in the context of</b>  16           <b>occupational medical practice for years.</b>  17           Q. Okay. And you would consider that clinical  18           experience in epidemiology?  19           <b>A. I certainly think so.</b>  20           Q. Would you agree --  21           Well how would you define the field of  22           epidemiology?  23           <b>A. I think epidemiology is the study of disease</b>  24           <b>in populations.</b>  25           Q. Okay. And how would one go about</p>	<p>1           <b>A. I've taken lots of statistics courses, but I</b>  2           <b>am not a statistician.</b>  3           Q. Okay. Were you the one who suggested  4           Professor Holford get involved in the case?  5           <b>A. I think I may have been the one who gave</b>  6           <b>Corey his name one day when Corey -- that is, Mr.</b>  7           <b>Gordon -- asked me for the names of some expert</b>  8           <b>statisticians.</b>  9           Q. Okay. And was that because you didn't feel  10           comfortable doing statistics work in the case?  11           <b>A. I gave the name to Mr. Gordon because he</b>  12           <b>asked me for the name of a world-class statistician.</b>  13           Q. Okay. Did --  14           Well you've read Professor Holford's report;  15           correct?  16           <b>A. I have read his report.</b>  17           Q. And do you feel that you, in the absence of  18           him, would have been comfortable writing the numbers  19           and doing the statistics that Professor Holford did?  20           <b>A. I probably would not have felt as</b>  21           <b>comfortable as he.</b>  22           Q. Okay. So it's on those issues you're  23           deferring to Professor Holford.  24           <b>A. I am relying upon Professor Holford.</b>  25           Q. Okay. Did you ever have any discussions</p>

5 (Pages 17 to 20)



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<p style="text-align: right;">Page 21</p> <p>1 with Professor Holford during the drafting of your 2 report?</p> <p>3 <b>A. No.</b></p> <p>4 Q. Okay. And when did you first see Professor 5 Holford's expert report?</p> <p>6 <b>A. I'm sorry, I don't remember, but it was 7 between --</b></p> <p>8 <b>It was probably in May, but I don't remember 9 the date.</b></p> <p>10 Q. Okay. And was that in draft form or final 11 form?</p> <p>12 <b>A. It may have been in draft form. I'm not 13 exactly clear.</b></p> <p>14 Q. Okay. Did you make any comments in terms of 15 edits or suggestions in connection with the report?</p> <p>16 <b>A. No.</b></p> <p>17 Q. Okay.</p> <p>18 <b>A. Sorry. Wait, wait. I -- I -- I corrected a 19 spelling error.</b></p> <p>20 Q. Okay. But other than that, you took the 21 report and that was, as we'll go through, incorporated 22 in part into some of the things that you have 23 testified to.</p> <p>24 <b>A. I am not aware that I suggested to Professor 25 Holford that he change anything.</b></p>	<p style="text-align: right;">Page 23</p> <p>1 Q. Okay. So you knew of his name before you 2 met him on May 8th.</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. Okay.</p> <p>5 MR. GORDON: Jan, sorry, I'm a little slow 6 on the draw. He -- he didn't know her, but I had an 7 associate with me named Micah Hines.</p> <p>8 THE WITNESS: I apologize.</p> <p>9 MS. CONLIN: No offense taken on this side.</p> <p>10 THE WITNESS: Thank you.</p> <p>11 Q. So if we can take a look at your report, and 12 I'd like to direct your attention to page two of Borak 13 Exhibit No. 1, paragraph nine --</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. Okay. In addition to the reference list, 16 which is contained on pages 24 through 27 of Exhibit 17 1, your June 2nd report, is this all of the material 18 that you reviewed? In other words, if I take 19 paragraph nine and I take your reference list, which 20 is contained on pages 24 through 27, is that the sum 21 total of the materials that you reviewed in connection 22 with your opinions in this case?</p> <p>23 <b>A. No.</b></p> <p>24 Q. Okay. What else did you review?</p> <p>25 <b>A. I reviewed a great amount of literature. I</b></p>
<p style="text-align: right;">Page 22</p> <p>1 Q. Okay. Setting that aside, my question is: 2 You looked at that for the purposes of incorporating 3 portions or reliance on portions of Professor 4 Holford's report in your report that's been marked 5 as --</p> <p>6 <b>A. Yes, that's correct.</b></p> <p>7 Q. -- Borak --</p> <p>8 <b>A. That's correct.</b></p> <p>9 Q. -- Deposition Exhibit No. 1. 10 Okay. Now you and Professor Holford were at 11 a May 8th meeting in Washington?</p> <p>12 <b>A. We were at a meeting. I'm not sure it was 13 May 8th. But yes, --</b></p> <p>14 Q. Okay.</p> <p>15 <b>A. -- that meeting in Washington.</b></p> <p>16 Q. And who else was present?</p> <p>17 <b>A. Mr. Gordon and Dr. Wenzel.</b></p> <p>18 Q. Okay.</p> <p>19 <b>A. I don't think there was anybody else.</b></p> <p>20 Q. Okay. And had you met Dr. Wenzel before?</p> <p>21 <b>A. No.</b></p> <p>22 Q. Okay. Did you know of him or of his work?</p> <p>23 <b>A. I know his name.</b></p> <p>24 Q. From what?</p> <p>25 <b>A. The medical literature.</b></p>	<p style="text-align: right;">Page 24</p> <p>1 <b>relied upon the references that you see enumerated.</b></p> <p>2 Q. Did you review any other depositions, 3 exhibits, or documents that were produced in this case 4 other than what you've listed in paragraph nine?</p> <p>5 <b>A. On -- only as I mentioned earlier this 6 morning.</b></p> <p>7 Q. Okay. And as I recall your testimony from 8 earlier this morning, it wasn't deposition testimony 9 or documents that were produced in the case; correct?</p> <p>10 <b>A. I don't know what you mean exactly by 11 "produced in the case," but I looked at a rough draft 12 of much of Dr. Holford's deposition.</b></p> <p>13 Q. Yeah. But other than that, with respect to 14 materials and depositions, exhibits and things that 15 have been produced in this case, the sum total of what 16 you reviewed is set forth in paragraph nine of your 17 report; correct?</p> <p>18 <b>A. I think that's correct, yes.</b></p> <p>19 Q. Okay.</p> <p>20 <b>A. I'm not aware of anything else which might 21 have been eligible for listing that I have not listed.</b></p> <p>22 Q. Okay.</p> <p>23 MR. GORDON: And -- and Jan, just so you're 24 clear, I don't -- the distinction may be unclear to 25 Dr. Borak, but the Ridgeview documents he reviewed</p>

6 (Pages 21 to 24)

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<p>1 were documents produced by Ridgeview --</p> <p>2 MS. CONLIN: Okay.</p> <p>3 MR. GORDON: -- pursuant to subpoena, not</p> <p>4 pursuant to a deposition.</p> <p>5 MS. CONLIN: Understood.</p> <p>6 Q. Let me ask it a different way. Prior to the</p> <p>7 time you rendered your opinions in this case on June</p> <p>8 2nd, 2017, does paragraph nine in your report set</p> <p>9 forth everything that you reviewed by way of</p> <p>10 depositions, transcripts, exhibits and documents</p> <p>11 produced in the case?</p> <p>12 <b>A. Yes, I think that is correct.</b></p> <p>13 Q. Now how did you go about deciding what you</p> <p>14 were going to review as reflected in paragraph nine?</p> <p>15 <b>A. I think most of these were sent to me by Mr.</b></p> <p>16 <b>Gordon's office.</b></p> <p>17 Q. Okay. So the documents and transcripts</p> <p>18 reflected in paragraph nine of your report were</p> <p>19 selected for you and sent to you by Mr. Gordon;</p> <p>20 correct?</p> <p>21 <b>A. They were sent to me by Mr. Gordon.</b></p> <p>22 Q. Okay. Did you ask him for them, or did they</p> <p>23 just arrive?</p> <p>24 <b>A. It was probably some conversation by phone</b></p> <p>25 <b>related to the fact that there were documents and they</b></p>	<p>1 <b>like to get you involved in this," and that day we</b></p> <p>2 <b>went from being friends to being client and</b></p> <p>3 <b>consultant.</b></p> <p>4 Q. And that was sometime in late April?</p> <p>5 <b>A. I think so.</b></p> <p>6 Q. How did you go about compiling the -- you</p> <p>7 said --</p> <p>8 In paragraph 10 you said, "I also reviewed a</p> <p>9 large number of scientific reports related to surgical</p> <p>10 warming devices, operating room procedures, surgical</p> <p>11 complications and infections, and other related</p> <p>12 medical and scientific issues." How did you go about</p> <p>13 gathering that information?</p> <p>14 <b>A. I'm trying to reconstruct the history as</b></p> <p>15 <b>clearly as I can. I -- I assume -- I'm not certain</b></p> <p>16 <b>but I assume that initially, after discussions with</b></p> <p>17 <b>Mr. Gordon, I was provided a packet of materials and</b></p> <p>18 <b>told that this was background materials, and that</b></p> <p>19 <b>probably would have included the studies from</b></p> <p>20 <b>Northumbria and that sort of thing. And I have in my</b></p> <p>21 <b>office a full-time librarian who does routinely</b></p> <p>22 <b>extensive literature searches for me using the Yale</b></p> <p>23 <b>library and the National Library of Medicine, and we</b></p> <p>24 <b>pick keywords and we search on things, and so sometime</b></p> <p>25 <b>after I had read those first papers I would have</b></p>
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<p>1 <b>would be sent. I think the one that I requested or</b></p> <p>2 <b>that came as a consequence of a request was the</b></p> <p>3 <b>deposition of Dr. Nachtsheim --</b></p> <p>4 Q. Yeah, Nachtsheim. Yeah.</p> <p>5 <b>A. N-a-c-h-t-s-h-t-e-i-m.</b></p> <p>6 <b>-- and that was a response to a statement</b></p> <p>7 <b>that was in Dr. Samet's report. I believe, if I</b></p> <p>8 <b>recall, Dr. Samet referred to an extended series of</b></p> <p>9 <b>cases or something of that sort -- I could look it up,</b></p> <p>10 <b>but I think you understand what I'm speaking to -- and</b></p> <p>11 <b>I said, "What is that?" And I was sent this add --</b></p> <p>12 <b>added material because I didn't understand that</b></p> <p>13 <b>statement from this Samet report.</b></p> <p>14 Q. Okay. When were you retained in this case?</p> <p>15 <b>A. Probably in late April, but I don't remember</b></p> <p>16 <b>specifically.</b></p> <p>17 Q. So the first time you were retained in this</p> <p>18 case was in late April after Dr. Samet had issued his</p> <p>19 report.</p> <p>20 <b>A. I -- I'm not sure of the chronology</b></p> <p>21 <b>specifically.</b></p> <p>22 <b>Mr. Gordon was somebody I have known for</b></p> <p>23 <b>some years. We had spoken of this. And I was not</b></p> <p>24 <b>retained or participating, and he was speaking to me</b></p> <p>25 <b>as a colleague friend, and one day he said, "I would</b></p>	<p>1 <b>identified a series of search strings. I might very</b></p> <p>2 <b>well have searched on the word -- or phrase "Bair</b></p> <p>3 <b>Hugger." I would have looked at literature on</b></p> <p>4 <b>orthopedic infections. In addition, from time to time</b></p> <p>5 <b>Mr. Gordon would send me articles, some of which might</b></p> <p>6 <b>have been more obscure than not. Some of them were</b></p> <p>7 <b>from some fairly-out-of-the-way English journals, and</b></p> <p>8 <b>for some of these I actually had to register with the</b></p> <p>9 <b>journals to be able to access their articles, and I</b></p> <p>10 <b>did so.</b></p> <p>11 Q. Do you have a record of what searches you</p> <p>12 performed or do you have the documents that you</p> <p>13 pulled, the articles, --</p> <p>14 <b>A. The answer --</b></p> <p>15 Q. -- in your office?</p> <p>16 <b>A. The answer to the first one is probably not,</b></p> <p>17 <b>but the answer to the second one is yes.</b></p> <p>18 MS. CONLIN: Okay. We're going to ask for a</p> <p>19 full list of all the publications that he pulled and</p> <p>20 reviewed in connection with his opinions in this case.</p> <p>21 Q. Would you agree with me -- I think you did,</p> <p>22 so I apologize for asking again -- but as a --</p> <p>23 When you're investigating an issue with your</p> <p>24 epidemiologist's hat on, it's important to have all</p> <p>25 the information in order to make your decision or</p>

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<p style="text-align: right;">Page 29</p> <p>1 opinion; correct?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 <b>A. I -- I would say that generalizes to many</b></p> <p>5 <b>fields, yes.</b></p> <p>6 Q. Okay. And did you ever ask the lawyers for</p> <p>7 3M for any of the other deposition transcripts or</p> <p>8 documents that have been produced in this case?</p> <p>9 <b>A. I -- I -- I'm not aware that I asked for</b></p> <p>10 <b>them.</b></p> <p>11 Q. Okay. Did you ask for any information</p> <p>12 relating to the Bair Hugger, how it's constructed or</p> <p>13 how it operates?</p> <p>14 <b>A. I believe I did, and I believe I received</b></p> <p>15 <b>some information, and I believe I made the point that</b></p> <p>16 <b>I was not a mechanical engineer and that I was not a</b></p> <p>17 <b>ventilation expert, that I was not a filtration</b></p> <p>18 <b>expert, and that I was not going to render an opinion</b></p> <p>19 <b>that relied upon such possible expertise.</b></p> <p>20 Q. What materials did you receive related to</p> <p>21 the Bair Hugger that aren't listed in exhibit nine?</p> <p>22 <b>A. I -- I can't recall what I've read. I mean</b></p> <p>23 <b>I've read certainly in depositions and in some of the</b></p> <p>24 <b>exhibits to some of the depositions, but I don't</b></p> <p>25 <b>specifically recall because it was not a field that I</b></p>	<p style="text-align: right;">Page 31</p> <p>1 between the Bair Hugger and a risk of infection?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, also misstates his testimony.</p> <p>4 <b>A. Yeah. I haven't said that there was</b></p> <p>5 <b>absolutely no association. I said I've seen no</b></p> <p>6 <b>evidence of any association; that was, other than two</b></p> <p>7 <b>troubled studies.</b></p> <p>8 Q. Okay. So that's why you've opined there is</p> <p>9 no association between the Bair Hugger and a risk of</p> <p>10 infection.</p> <p>11 <b>A. I have opined that I have seen no evidence</b></p> <p>12 <b>that there is an association, except for two troubled</b></p> <p>13 <b>studies.</b></p> <p>14 Q. Right. And my point is is without</p> <p>15 understanding how the machine operates, is --</p> <p>16 Is it just these two studies and that's what</p> <p>17 you did, and you found those studies to have issues so</p> <p>18 your conclusion is based on that?</p> <p>19 <b>A. I -- I have looked at the literature and</b></p> <p>20 <b>found no evidence of infections associated with use of</b></p> <p>21 <b>the Bair Hugger, which I understand to be a very-</b></p> <p>22 <b>large-volume-used instrument, and the only evidence</b></p> <p>23 <b>which I have seen to suggest that it causes infection</b></p> <p>24 <b>are the two papers that have been linked to Dr.</b></p> <p>25 <b>Augustine.</b></p>
<p style="text-align: right;">Page 30</p> <p>1 <b>was looking at specifically.</b></p> <p>2 Q. Well don't you think it's important, if</p> <p>3 you're trying to ascertain whether use of the Bair</p> <p>4 Hugger increases a risk of an infection, that you</p> <p>5 understand how it operates?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question.</p> <p>8 <b>A. I thought that the relevant question was</b></p> <p>9 <b>whether the Bair Hugger was associated with infection,</b></p> <p>10 <b>and so I really focused on the issue of whether there</b></p> <p>11 <b>were infections.</b></p> <p>12 Q. But in connection with looking at whether</p> <p>13 it's associated with infections, you didn't think it</p> <p>14 was important to understand how the device operates?</p> <p>15 <b>A. I thought I understood enough in principle</b></p> <p>16 <b>in how it operated, but I was not going to be opining</b></p> <p>17 <b>upon whether, for example, the motor was too large or</b></p> <p>18 <b>too small, or whether the filters were too large or</b></p> <p>19 <b>too small, or -- and -- and so forth, that I was not</b></p> <p>20 <b>going to be rendering that kind of an opinion and that</b></p> <p>21 <b>that was not my area of expertise.</b></p> <p>22 Q. Well if -- if you don't know how the machine</p> <p>23 operates, take into account, for example, the filter</p> <p>24 or the -- the efficiency of the filter, how is it that</p> <p>25 you can opine that there is absolutely no association</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. What do you mean "linked to Dr. Augustine?"</p> <p>2 Setting aside the new Augustine publication,</p> <p>3 which is self-evident, explain what you mean.</p> <p>4 You're -- you're referencing Augustine and</p> <p>5 McGovern; correct?</p> <p>6 <b>A. Correct.</b></p> <p>7 Q. Okay.</p> <p>8 <b>A. Well my understanding is that the McGovern</b></p> <p>9 <b>paper was largely if not entirely funded by Dr.</b></p> <p>10 <b>Augustine, and that the analyses were performed by a</b></p> <p>11 <b>member of his staff.</b></p> <p>12 Q. Do you think that funding of a study by a</p> <p>13 particular party undercuts its scientific validity?</p> <p>14 <b>A. It does not necessarily undercut its</b></p> <p>15 <b>scientific validity.</b></p> <p>16 Q. Okay. So why were you referencing that the</p> <p>17 McGovern study in your mind was funded by Augustine?</p> <p>18 <b>A. I -- I said they were associated with Dr.</b></p> <p>19 <b>Augustine and you asked me to clarify what I meant by</b></p> <p>20 <b>"associated," and I tried to explain that.</b></p> <p>21 Q. Why did you think that was important, to</p> <p>22 suggest that these two studies had some involvement by</p> <p>23 Augustine?</p> <p>24 <b>A. I --</b></p> <p>25 Q. And by the way, I'm not accepting your</p>

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<p style="text-align: right;">Page 33</p> <p>1 premise, but why -- why did you think that was 2 important?</p> <p>3 <b>A. I -- I simply used that to describe. But I</b> 4 <b>can take back the description. The description is</b> 5 <b>unimportant. The point I was making is that to the</b> 6 <b>best of my knowledge, having looked at a lot of the</b> 7 <b>literature, the only two studies that have proposed an</b> 8 <b>association between the use of the Bair Hugger and</b> 9 <b>infection are the McGovern and the Augustine papers.</b></p> <p>10 Q. Okay. You would agree with me that funding 11 of a particular study does not suggest on its face 12 that there's a problem with it; correct?</p> <p>13 <b>A. It always raises suggestions. I deal with</b> 14 <b>that every time that I have worked for a funding</b> 15 <b>source that might have been regarded as a source of</b> 16 <b>conflict of interest. It's one of the things I'm</b> 17 <b>constantly aware of in my own work, and I'm aware of</b> 18 <b>it in others', and I'm aware of it when I sit on an</b> 19 <b>editorial board and peer review other people's</b> 20 <b>submissions.</b></p> <p>21 Q. And your position is that as a scientist, 22 you're -- you're for hire but your opinions are not 23 for hire; correct?</p> <p>24 <b>A. There's something vulgar about the way you</b> 25 <b>say it, but the fact of the matter is that my opinions</b></p>	<p style="text-align: right;">Page 35</p> <p>1 <b>Reed is a well known orthopedic surgeon. I think Dr.</b> 2 <b>McGovern was probably a junior to Dr. Reed.</b></p> <p>3 Q. Okay. Was there a reason why you didn't 4 read Dr. Belani's deposition?</p> <p>5 <b>A. I frankly wasn't aware that there was a</b> 6 <b>deposition of Dr. Belani.</b></p> <p>7 Q. Okay. Well one of the things that you 8 suggest about the McGovern study is that there was 9 potentially data manipulation; correct?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. Okay.</p> <p>12 <b>A. Potentially.</b></p> <p>13 Q. All right. When making that accusation, 14 wouldn't it be important to look at the credentials of 15 the people against whom you're making that accusation?</p> <p>16 <b>A. Unfortunately, the credentials are not</b> 17 <b>the -- the assurance of probity.</b></p> <p>18 Q. Well you'd have to look and see whether 19 these were the type of individuals that would 20 manipulate data; correct?</p> <p>21 MR. GORDON: Object to the form of the 22 question, also lack of foundation.</p> <p>23 <b>A. I have, as a member of an editorial board,</b> 24 <b>been required to vote for the retraction of an article</b> 25 <b>from authors who have been extraordinarily well</b></p>
<p style="text-align: right;">Page 34</p> <p>1 <b>are not for sale, only my time.</b></p> <p>2 Q. Okay. And you would expect that to be the 3 case for any legitimate doctor or scientist that's 4 investigating an issue; correct?</p> <p>5 <b>A. One would hope.</b></p> <p>6 Q. Okay. 7 (Discussion off the stenographic record.) 8 BY MS. CONLIN: 9 Q. I have handed you, sir, what's been marked 10 previously as Holford Deposition Exhibit 13, which is 11 the McGovern paper that we've been discussing; 12 correct?</p> <p>13 <b>A. Correct.</b></p> <p>14 Q. Do you know any of the authors on this 15 paper?</p> <p>16 <b>A. I have read a lot of their work, but I never</b> 17 <b>met any.</b></p> <p>18 Q. Okay. Did you -- 19 Do you know who Dr. Belani is, for example?</p> <p>20 <b>A. I would be unable to describe him.</b></p> <p>21 Q. Okay. Do you know where he works?</p> <p>22 <b>A. I could look it up, but I don't.</b></p> <p>23 Q. Okay. How about Drs. McGovern or Reed?</p> <p>24 <b>A. Well I'm familiar with Dr. McGovern and Reed</b> 25 <b>as part of the Northumberland Health Trust. But Dr.</b></p>	<p style="text-align: right;">Page 36</p> <p>1 <b>credentialed. I don't think that that is necessarily</b> 2 <b>the assurance. It helps, but it does not assure.</b></p> <p>3 Q. Well which one of these McGovern -- 4 McGovern authors are you suggesting engaged in data 5 manipulation?</p> <p>6 <b>A. I -- I don't know which ones. I have their</b> 7 <b>depositions. I've cited from their depositions. They</b> 8 <b>agree, for example, that the published data differed</b> 9 <b>from the final data.</b></p> <p>10 <b>If I could look at my notes -- or not my</b> 11 <b>notes, but my report, I have citations specifically to</b> 12 <b>their depositions, and I was using their words.</b></p> <p>13 Q. Okay. My question is a little different, so 14 try to answer mine. My question is: Which of these 15 authors are you suggesting engaged in data 16 manipulation?</p> <p>17 MR. GORDON: Object to the form of the 18 question.</p> <p>19 <b>A. I -- I -- I don't have information to tell</b> 20 <b>me which ones did. I understand, from the sequence of</b> 21 <b>deposition information, that Dr. Reed at some point in</b> 22 <b>his deposition said, "It's clear to me that some of</b> 23 <b>the data on the clinical side are wrong," that Mr.</b> 24 <b>Albrecht says, "It looks like it didn't line up a</b> 25 <b>hundred percent. I'm not sure what's going on," Dr.</b></p>

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<p style="text-align: right;">Page 37</p> <p>1 Reed and Albrecht said, "There are differences." And</p> <p>2 I don't know --</p> <p>3 You're asking me who is personally and</p> <p>4 individually responsible. I don't know the answer to</p> <p>5 that.</p> <p>6 Q. Okay. You --</p> <p>7 Did you read the whole depositions?</p> <p>8 A. I did at some point, yes, absolutely.</p> <p>9 Q. Okay. How did you decide the quotes that</p> <p>10 you put in your report? Were those ones that were</p> <p>11 suggested to you by 3M?</p> <p>12 A. No, absolutely not.</p> <p>13 Q. So they were ones you chose.</p> <p>14 A. Yes.</p> <p>15 Q. Well you know that Dr. Reed testified that</p> <p>16 "The data file for the paper was definitely correct.</p> <p>17 I checked it multiple times." Correct?</p> <p>18 A. I --</p> <p>19 He may have said that, but he also said that</p> <p>20 there were mistakes and that there was additional</p> <p>21 cases.</p> <p>22 Q. You're referring to his testimony that he</p> <p>23 thought maybe there was an additional infection in</p> <p>24 each group?</p> <p>25 A. I believe that's how he testified, correct.</p>	<p style="text-align: right;">Page 39</p> <p>1 those two documents. I understand that that has been</p> <p>2 done by Dr. Holford, and I rely upon Dr. Holford's</p> <p>3 ability to do that.</p> <p>4 Q. Okay. So with respect to the veracity of</p> <p>5 McGovern Exhibit 16 or Albrecht Exhibit 10 and what it</p> <p>6 shows or doesn't show, you're relying on Professor</p> <p>7 Holford on that.</p> <p>8 A. In terms of the statistics and the matching</p> <p>9 up of the case numbers and those sorts of things, yes,</p> <p>10 I'm ultimately relying upon Dr. Holford.</p> <p>11 (Exhibit 3 was marked for</p> <p>12 identification.)</p> <p>13 BY MS. CONLIN:</p> <p>14 Q. I've handed you, sir, what's been marked as</p> <p>15 Borak Deposition No. 3, which is a page off of your</p> <p>16 company website; correct?</p> <p>17 A. Correct.</p> <p>18 Q. And this was founded in what, 1988?</p> <p>19 A. That sounds right.</p> <p>20 Q. Okay.</p> <p>21 A. '86 I think.</p> <p>22 Q. And how many people are employed at Jonathan</p> <p>23 Borak &amp; Company?</p> <p>24 A. Currently there are four full time.</p> <p>25 Q. Okay. And how much of your time do you</p>
<p style="text-align: right;">Page 38</p> <p>1 Q. Okay. And that was a deposition that was</p> <p>2 taken, what, years after the publication; correct?</p> <p>3 A. I guess so, but I don't know for sure.</p> <p>4 Q. So how did you --</p> <p>5 If you think that one or more of these</p> <p>6 authors engaged in data manipulation, how did you</p> <p>7 decide what you were going to rely on from their</p> <p>8 depositions and what you were going set aside as being</p> <p>9 false?</p> <p>10 A. I can't construct or reconstruct my thought</p> <p>11 at the time that I read these things, but these</p> <p>12 statements struck me as being supportive of the fact</p> <p>13 that there were some differences in the data and that</p> <p>14 the published data were not the final data.</p> <p>15 Q. Did you do any investigation into the data</p> <p>16 tabulation sets which have been marked as and referred</p> <p>17 to as McGovern Exhibit 16 or Albrecht Exhibit 10?</p> <p>18 A. I have -- I have looked at both. If I'm</p> <p>19 correct, the Albrecht Exhibit 10 is a very, very thick</p> <p>20 document, and I have leafed through it in part trying</p> <p>21 to see if I could locate in there the individual who</p> <p>22 was identified in the McGovern Exhibit 16 as case</p> <p>23 number 44. If I'm correct, that one is a rather</p> <p>24 small, much more concise document. But I have not</p> <p>25 made any kind of definitive effort to review either of</p>	<p style="text-align: right;">Page 40</p> <p>1 spend as a consultant, under the umbrella of Jonathan</p> <p>2 Borak &amp; Company, versus teaching?</p> <p>3 A. Probably 85 percent or more.</p> <p>4 Q. Is through Jonathan Borak &amp; Company?</p> <p>5 A. That's correct.</p> <p>6 Q. And of that 85 percent of your time, how</p> <p>7 much is in consulting versus litigation?</p> <p>8 A. I'm sorry. So the distinction you're saying</p> <p>9 is consulting that is not litigation-based.</p> <p>10 Q. Right.</p> <p>11 A. Let -- let me step back. I --</p> <p>12 Just to be clear, many if not all of my</p> <p>13 clients -- not all, but most of my clients are</p> <p>14 lawyers. Often I am approached by lawyers to do non-</p> <p>15 litigation work or work that is not directly relevant</p> <p>16 to my being an expert in a litigation. For example,</p> <p>17 we recently were involved in doing a vetting of a</p> <p>18 company's website and documentation prior to an</p> <p>19 acquisition. We did that for an attorney. I have</p> <p>20 done work in the regulatory area and I'm almost always</p> <p>21 approached by an attorney. But the answer is I think</p> <p>22 that I have testified perhaps four or five times in</p> <p>23 the past four years, and I do a variety of different</p> <p>24 kinds of work. I would guess, because it's not</p> <p>25 constant, but I would guess that about 30 percent or</p>

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<p style="text-align: right;">Page 41</p> <p>1 so of my income is litigation-related.</p> <p>2 Q. Thirty percent of your income from the</p> <p>3 Jonathan Borak &amp; Company.</p> <p>4 A. I would guess, yes.</p> <p>5 Q. Okay.</p> <p>6 A. And yes, I think that's correct.</p> <p>7 Q. Okay. Now you indicate here that you serve</p> <p>8 mainly to Fortune 500 companies and their</p> <p>9 representatives, government agencies, national labor</p> <p>10 unions, and professional societies; is that fair?</p> <p>11 A. I think so.</p> <p>12 Q. Okay. In the past two decades, to the</p> <p>13 extent that you've done work in litigation, --</p> <p>14 A. Yes.</p> <p>15 Q. -- it's been for the defense; correct?</p> <p>16 A. What time period was that?</p> <p>17 Q. Last two decades.</p> <p>18 A. At one time I did a lot of plaintiffs' work.</p> <p>19 Over the recent past it has been predominantly</p> <p>20 defense, but I do some lit -- plaintiffs' side.</p> <p>21 Q. Okay. In the last decade, have you done a</p> <p>22 single case on the plaintiffs' side?</p> <p>23 A. I have not testified on the plaintiffs'</p> <p>24 side, but I have done plaintiffs'-side work.</p> <p>25 Q. What types of cases?</p>	<p style="text-align: right;">Page 43</p> <p>1 A. I have done a number of such pieces of work.</p> <p>2 Q. And the issue was whether there was</p> <p>3 causation presented by the silica.</p> <p>4 A. Whether silica was sufficient a causation</p> <p>5 that it belonged in one pot rather than in the other</p> <p>6 pot, yes.</p> <p>7 Q. Okay. Have you ever in litigation, just</p> <p>8 putting on your litigation hat, opined that exposure</p> <p>9 to an environmental toxin caused harm?</p> <p>10 A. In a litigation context.</p> <p>11 I've certainly written that it can. I don't</p> <p>12 know that I have in a specific litigation context.</p> <p>13 Q. In fact, in the litigation context every</p> <p>14 single one of your retentions resulted in you opining</p> <p>15 that whatever the exposure to an environmental toxin</p> <p>16 was didn't cause the harm alleged by the injured</p> <p>17 person; correct?</p> <p>18 A. I -- I think that you misrepresent my</p> <p>19 opinions. I've been in a number which have to do with</p> <p>20 concerns about what was known and when was it known</p> <p>21 and whether a particular entity was responsible, and I</p> <p>22 don't think any of those opinions suggested that the</p> <p>23 claimants were uninjured. There may have been some</p> <p>24 cases where I have said that, but I think that many of</p> <p>25 my opinions have dealt with questions of the</p>
<p style="text-align: right;">Page 42</p> <p>1 A. Water contamination by perfluorooctanoic</p> <p>2 acid.</p> <p>3 Q. Anything else?</p> <p>4 A. That was the largest one recently. There</p> <p>5 have been others. Sometimes it's not clear to me who</p> <p>6 is a plaintiff or a defendant. I know that sounds</p> <p>7 peculiar. But I was involved in a very large</p> <p>8 situation of a company that had acquired a division</p> <p>9 from another company that made respirators, and as</p> <p>10 part of the acquisition the seller retained certain</p> <p>11 historical liabilities and the acquirers accepted</p> <p>12 other liabilities, and it became a question of whether</p> <p>13 coal miners' pneumoconiosis could develop in the</p> <p>14 absence of silica. There was no question of damages</p> <p>15 to individuals in the sense that it was not a question</p> <p>16 of whether somebody was or was not going to get</p> <p>17 compensation, it was a question of which insurance</p> <p>18 pool was going to pay for it. That -- that is</p> <p>19 something where it's a litigation-based piece of work,</p> <p>20 but I don't see it as being plaintiff and defense as</p> <p>21 you raised the question.</p> <p>22 Q. Yes. It was an issue of retained</p> <p>23 liabilities versus assumed liabilities.</p> <p>24 A. In that particular case.</p> <p>25 Q. And in that case --</p>	<p style="text-align: right;">Page 44</p> <p>1 adjudication of responsibility.</p> <p>2 Q. My question was a little different. When</p> <p>3 you've opined on causation in the litigation context,</p> <p>4 there hasn't been a single time where you have found</p> <p>5 that an environmental toxin caused harm in an</p> <p>6 individual.</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question, also asked and answered.</p> <p>9 A. Yeah. I'm -- I'm not sure that I can</p> <p>10 remember --</p> <p>11 I mean it may -- it may be that when I</p> <p>12 render such an opinion, people decide to settle their</p> <p>13 cases. I don't know.</p> <p>14 Q. Can you --</p> <p>15 As you sit here today, can you think of a</p> <p>16 single instance in the last two decades where in the</p> <p>17 litigation context you have opined that exposure to a</p> <p>18 particular environmental toxin or otherwise caused</p> <p>19 harm in an individual?</p> <p>20 A. I -- I can't remember a specific example of</p> <p>21 the other side either, so perhaps you can help me.</p> <p>22 Q. Okay. Well we'll go through them. But as</p> <p>23 you sit here, can you name one?</p> <p>24 A. I don't know that I can name one to the</p> <p>25 other side. Most of what I have done has involved --</p>

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<p>1 Well let me go back. With the exception 2 of -- 3 Where I have testified. 4 Q. Not where you've testified, where you've 5 rendered an expert opinion in a case, whether it be 6 through trial, deposition, or a report -- 7 A. Well I think a deposition -- 8 Okay. Report. I -- I've written reports 9 and I have never known whatever happened to those 10 things. In some cases I felt that there was -- 11 Oftentimes, people ask me not to write 12 reports when I don't agree with their view, so when 13 defense lawyers ask me whether I think A causes B and 14 I say yes, they say thank you, and it never progresses 15 beyond that. 16 Q. Can you answer my question? 17 A. What is your question? 18 Q. My question is: As you sit here today, can 19 you identify a single instance in which you've 20 rendered an expert opinion in litigation that exposure 21 to an environmental toxin caused harm in an 22 individual? 23 MR. GORDON: Object to the form of the 24 question, asked and answered. 25 A. Most recently I have spent a fair amount of</p>	<p>1 identification.) 2 BY MS. CONLIN: 3 Q. I've handed you, sir, what's been marked as 4 Borak Deposition Exhibit No. 4, which is an article 5 authored by you and others entitled "Mortality 6 Disparities in Appalachia." 7 A. Yes. 8 Q. Okay. And this was a study that you 9 authored that was funded entirely by the National 10 Mining Association; correct? 11 A. Yes, that's correct. 12 Q. And you wouldn't suggest that because the 13 National Mining Association funded this study, that 14 that somehow taints this; correct? 15 A. No. They were unhappy with it. 16 Q. Okay. And in this you conclude that there 17 hasn't been any solid epidemiological evidence that 18 coal mining increased risks to population health in 19 the Appalachia region; correct? 20 A. I think you misspeak it. I -- I think that 21 what we found was "...that coal mining in Appalachia, 22 an industrial activity associated with rural, 23 mountainous areas, is likely to be geographically 24 associated with a variety of economic and cultural 25 health risk factors. And, for similar reasons, mining</p>
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<p>1 time looking at these perfluorooctanoic acid exposures 2 and I have offered verbal reports but I have not 3 written reports, and the reports were that there was 4 causation. 5 Q. Okay. Can you answer my question though? 6 In terms of -- 7 A. I -- I cannot remember is the answer. 8 Q. Okay. When did you become a consultant to 9 the National Mining Association? 10 A. I don't remember the date. 11 Q. Okay. 12 MR. GORDON: Let me interrupt. I'm -- 13 I'm -- I'm -- 14 The section where he discusses his -- 15 whatever he did with PFOA, I have no idea where that 16 is in the litigation process, I'm not involved in it, 17 but I -- it sounds to me like something that probably 18 ought to be marked as confidential. 19 MS. CONLIN: I don't have an issue with 20 that. 21 Q. You authored a study that was funded by the 22 National Mining Association; correct? 23 A. Remind me of the title. 24 Q. Sure. 25 (Exhibit 4 was marked for</p>	<p>1 is also likely to be geographically associated with a 2 variety of adverse health outcomes. Although our 3 results indicate that mining is not the direct cause 4 of those outcomes, they do not rule out the 5 possibility that mining contributes to the development 6 of the social environments and cultural practices that 7 adversely impact health." 8 Q. Right. 9 A. My belief was and is that it is not 10 pollution from the coal mines but social pollution 11 from the industry that has caused these disparities. 12 Q. Right. That there is no direct link between 13 coal mining and adverse health outcomes. 14 A. No, no. I think that the coal mining 15 industry and its social context has contributed to 16 these adverse effects. 17 Q. Well let's take a look at the last page -- 18 well, second-to-the-last page. I think it's got an 19 internal number 154. Direct your attention to the 20 right-hand side, first full paragraph starting with 21 "Accordingly..." and direct your attention down to the 22 sentence, "Although our results indicate that mining 23 is not the direct cause of those outcomes, they do not 24 rule out the possibility that mining contributes to 25 the development of social environments and cultural</p>

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<p style="text-align: right;">Page 49</p> <p>1 practices that adversely impact health."</p> <p>2 <b>A. That's the sentence I just read to you.</b></p> <p>3 Q. Okay. And you find that mining is not a</p> <p>4 direct cause of the -- and it's your word, "direct</p> <p>5 cause" -- of the health -- strike that.</p> <p>6 Let me say you find that mining itself is</p> <p>7 not a direct cause of illness in a population;</p> <p>8 correct?</p> <p>9 <b>A. Yes, that it was the -- the mining</b></p> <p>10 <b>industry's influence on the social environment.</b></p> <p>11 Q. Right. People are getting black lung</p> <p>12 disease because they're overweight and poor.</p> <p>13 <b>A. The people who were suffering health</b></p> <p>14 <b>disparities in this community were not miners and they</b></p> <p>15 <b>were not getting black lung.</b></p> <p>16 Now in fact we make mention here that it is</p> <p>17 not because of the miners that there were these health</p> <p>18 disparities and that the disparities existed in both</p> <p>19 males and females, although the females did not work</p> <p>20 in the mines. Black lung is a disease of occupation.</p> <p>21 That's not the issue of concern in this paper.</p> <p>22 Q. Well you were actually interviewed a bunch</p> <p>23 in connection with this article; weren't you? It</p> <p>24 caused quite a stir; correct?</p> <p>25 <b>A. I don't know that it caused quite a stir,</b></p>	<p style="text-align: right;">Page 51</p> <p>1 over a study involving mold; correct?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 <b>A. There was controversy about a position paper</b></p> <p>5 <b>that was written by The American College of</b></p> <p>6 <b>Occupational Envi -- that was posted by The American</b></p> <p>7 <b>College of Occupational Environmental Medicine. I was</b></p> <p>8 <b>the chairman of the committee that oversaw the</b></p> <p>9 <b>development of the paper. I didn't write it and I had</b></p> <p>10 <b>little other than the fact that I kept the editorial</b></p> <p>11 <b>process going.</b></p> <p>12 Q. All right. And that paper found that there</p> <p>13 are no adverse health effects associated with toxic</p> <p>14 mold; correct?</p> <p>15 <b>A. No, that's not what it found.</b></p> <p>16 Q. What's your understanding of what it found?</p> <p>17 <b>A. What it found was that mold could cause a</b></p> <p>18 <b>number of allergic and irritative disorders, but that</b></p> <p>19 <b>which became known as, quote, unquote, toxic mold</b></p> <p>20 <b>syndrome was not; it had not been documented. It was</b></p> <p>21 <b>written by a former deputy director of The National</b></p> <p>22 <b>Institute of Occupational Safety and Health. I didn't</b></p> <p>23 <b>write it.</b></p> <p>24 Q. Correct. But you -- you reviewed it as part</p> <p>25 of your role as director on -- at --</p>
<p style="text-align: right;">Page 50</p> <p>1 <b>but I think I had a couple of interviews.</b></p> <p>2 Q. And you said the health effects due to coal</p> <p>3 and coal mining is just not known; correct?</p> <p>4 <b>A. I'm sorry?</b></p> <p>5 Q. You -- you were quoted as saying the health</p> <p>6 effects due to coal and coal mining is just not known;</p> <p>7 correct?</p> <p>8 <b>A. Regarding people in the community.</b></p> <p>9 Q. And in fact you said, quote, "The problem is</p> <p>10 that the theory that this is due to coal and coal</p> <p>11 pollution is politically attractive but scientifically</p> <p>12 not defensible;" correct?</p> <p>13 <b>A. That sounds like something I would have</b></p> <p>14 <b>said.</b></p> <p>15 Q. Okay. And you said, quote, "It may or may</p> <p>16 not be due to coal mining, I actually don't know, but</p> <p>17 I think it could be, but it's not due to the coal;"</p> <p>18 correct?</p> <p>19 <b>A. That sounds right.</b></p> <p>20 Q. Okay. And you said while the work was</p> <p>21 funded by the National Mining Association, quote, your</p> <p>22 time is for hire, your opinions are not.</p> <p>23 <b>A. Okay. That sounds like something I said to</b></p> <p>24 <b>you earlier today.</b></p> <p>25 Q. You were also caught up in some controversy</p>	<p style="text-align: right;">Page 52</p> <p>1 Do you say -- how do you say it, A-C-O-E-M?</p> <p>2 <b>A. Or ACOEM if you --</b></p> <p>3 Q. ACOEM. Okay.</p> <p>4 And you knew before it was published that</p> <p>5 the authors were experts for the defense in mold</p> <p>6 litigation; correct?</p> <p>7 <b>A. No. To the contrary, Dr. Hardin told me he</b></p> <p>8 <b>was not specifically.</b></p> <p>9 Q. Okay. But e-mails came to light after that</p> <p>10 publication which suggested that you did know before</p> <p>11 publication.</p> <p>12 <b>A. Would you read that to me? I'm not aware</b></p> <p>13 <b>that I was aware that Dr. Hardin had been an expert.</b></p> <p>14 <b>To the contrary.</b></p> <p>15 Q. Okay.</p> <p>16 <b>A. It also might be useful for the record to</b></p> <p>17 <b>note the date that this was: it's about like 15 years</b></p> <p>18 <b>ago.</b></p> <p>19 Q. Yeah. It was in 2002; right?</p> <p>20 <b>A. Fifteen years ago.</b></p> <p>21 Q. Yeah. Did you think that there was anything</p> <p>22 that was -- undercut it -- undercut the validity of</p> <p>23 that study because the authors were associated with</p> <p>24 the defense?</p> <p>25 <b>A. Dr. Hardin specifically told me that he was</b></p>

13 (Pages 49 to 52)



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<p style="text-align: right;">Page 53</p> <p>1 not, and he gave me a statement of conflict of</p> <p>2 interest, and I shared that with the board of ACOEM at</p> <p>3 the time.</p> <p>4 Q. My question was a little different. Did --</p> <p>5 did you think, when you found out that they</p> <p>6 represented the defense in that litigation, that that</p> <p>7 somehow impugned the veracity of the findings in that</p> <p>8 paper?</p> <p>9 A. When you say "that litigation," I am not</p> <p>10 sure which litigation you speak to. I understood that</p> <p>11 subsequently Dr. Hardin and his colleagues did opine</p> <p>12 in litigation for the defense.</p> <p>13 Q. Okay. And do you think, that they did that,</p> <p>14 that undercuts at all the scientific veracity of the</p> <p>15 paper you reviewed?</p> <p>16 A. I thought the paper was fair. And it was</p> <p>17 sent to a large, large, large number of peer</p> <p>18 reviewers. I did not make the decision as to publish</p> <p>19 or not.</p> <p>20 Q. My question is: Do you think the fact that</p> <p>21 they represented the defense undercuts at all the</p> <p>22 scientific veracity of the paper?</p> <p>23 A. No.</p> <p>24 MR. GORDON: Could we take a potty break</p> <p>25 fairly soon?</p>	<p style="text-align: right;">Page 55</p> <p>1 the College, or at least those concerned enough to</p> <p>2 voice their views;" correct?</p> <p>3 A. I'm sorry, say that again.</p> <p>4 Q. There was concerns about the college about</p> <p>5 publishing this review; correct?</p> <p>6 A. I was concerned that this particular review</p> <p>7 was polarizing the college members.</p> <p>8 Q. Right. And you write here though, "Even</p> <p>9 though a great deal of work has gone in, it seems</p> <p>10 difficult to satisfy a sufficient spectrum of the</p> <p>11 College, or at least those concerned enough to voice</p> <p>12 their views."</p> <p>13 A. Correct.</p> <p>14 Q. Okay. And then you go on in the next</p> <p>15 paragraph to suggest that if you officially reject it,</p> <p>16 then you turn Mr. Grove's efforts into garbage;</p> <p>17 correct?</p> <p>18 A. No, this mis --</p> <p>19 Q. Or to --</p> <p>20 A. It was Dr. --</p> <p>21 It was Bryan, Dr. Hardin's efforts.</p> <p>22 Q. Okay. So you were concerned if the college</p> <p>23 rejected it, Dr. Hardin's efforts would be turned into</p> <p>24 garbage; correct?</p> <p>25 A. I --</p>
<p style="text-align: right;">Page 54</p> <p>1 MS. CONLIN: Yeah. We can stop here if</p> <p>2 you'd like.</p> <p>3 THE REPORTER: Off the record, please.</p> <p>4 (Recess taken.)</p> <p>5 (Exhibit 5 was marked for</p> <p>6 identification.)</p> <p>7 THE WITNESS: Thank you.</p> <p>8 BY MS. CONLIN:</p> <p>9 Q. I've handed you, sir, what's been marked as</p> <p>10 Borak Exhibit No. 5, and this is the e-mail that we</p> <p>11 were talking about just before the break as it relates</p> <p>12 to your role at ACOEM and the publication of an</p> <p>13 article by Dean Grove; is that right?</p> <p>14 A. Yes. He was then president of the college.</p> <p>15 Q. Okay. And this related --</p> <p>16 This is dated September 6th, 2002, and this</p> <p>17 relates to the review by ACOEM of the article -- or</p> <p>18 the study that was going to be published on whether --</p> <p>19 A. It was not a study, it was a review.</p> <p>20 Q. -- whether a review was going to be</p> <p>21 published; correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Okay. And in this e-mail you indicated that</p> <p>24 "Even though a great deal of work has gone in, it</p> <p>25 seems difficult to satisfy a sufficient spectrum of</p>	<p style="text-align: right;">Page 56</p> <p>1 It sounds right, but show me where the word</p> <p>2 "garbage" is. I'm sorry.</p> <p>3 Q. If you look at the last full sentence in the</p> <p>4 second paragraph, "That would be an important</p> <p>5 violation" --</p> <p>6 A. Yes. Okay. Fine. I do see it. I just</p> <p>7 want to make sure I used that word.</p> <p>8 Q. You write, "That would be an important</p> <p>9 violation of Bryan -- I have assured him that if we</p> <p>10 do not use it he can freely make whatever other use he</p> <p>11 might want to make. If we 'officially' reject it,</p> <p>12 then we turn his efforts into garbage." Correct?</p> <p>13 A. Correct.</p> <p>14 Q. And that was the concern, that if the paper</p> <p>15 didn't get published and was rejected by the college,</p> <p>16 then the paper might not gain traction.</p> <p>17 A. No, that was not the concern.</p> <p>18 Q. What was your concern?</p> <p>19 A. My concern was that Bryan was a very</p> <p>20 respected scientist. I knew that he had interest in</p> <p>21 mold because I had seen some of his writings. At that</p> <p>22 time he was not, as I understood it, involved in the</p> <p>23 issue other than as a scientific issue. I asked him</p> <p>24 whether he would be willing to prepare this review for</p> <p>25 purposes of the college and he agreed to do that. He</p>

14 (Pages 53 to 56)

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<p style="text-align: right;">Page 57</p> <p>1 spent quite a while putting a paper together. He sent  2 it to me. I sent it out to my panel of reviewers;  3 there may have been 20 or 30 or more people in the  4 college who reviewed it. They gave me back feedback.  5 And I returned it to Dr. Hardin and I said this is  6 what people think, it's too polarized, it's too this,  7 it's too that, it's not enough this, it's not enough  8 of that, "Are you prepared to change it?" And he said  9 "Yes." And so he then spent quite a bit of time  10 rewriting, and not different than what happens when I  11 sit on a journal review and somebody sends a paper in  12 and it goes back with comments from the reviewers  13 which says "Major revision required." And so the  14 major revision was done and it was sent back. And I  15 returned that to the reviewers and they sent back  16 comments to me. And I sent those comments back to  17 Bryan and I said, "It's better, but it's still not  18 sufficient for me to put it before the board of  19 directors because it's too polarizing, and I would  20 like you to address that these are the issues that  21 people are raising." And he revised it again and he  22 sent it back to me. And I sent it out to reviewers  23 and I said, "Does this answer your concerns?" And  24 there were people who came back with continuing  25 concerns. And so then I had the following problem,</p>	<p style="text-align: right;">Page 59</p> <p>1 talk. I was invited -- I don't even remember who  2 invited me, but I was with the Dean of Hastings Law  3 School.  4 Q. I didn't ask you about any of this.  5 A. Okay.  6 Q. My question was a simple one. You were a  7 faculty member at BRI, which is a defense bar, in a  8 toxic tort seminar; correct?  9 A. Yes. I spoke about peer review in the  10 scientific process, I think in March of this year.  11 Q. Okay. And that's the only time that you  12 think you've done that?  13 A. I'm not aware of having done it other --  14 It's possible, but I certainly don't  15 remember it. And it wasn't recent.  16 Q. Okay. Do you agree with me that the  17 Bradford-Hill criteria is an appropriate methodology  18 for addressing an epidemiological issue?  19 MR. GORDON: Object to the form of the  20 question.  21 A. It's been adopted as a methodology. It's  22 not really a methodol -- a methodology, it's a set of  23 viewpoints.  24 Q. Okay. Would you agree with me that  25 observational epidemiological studies can yield data</p>
<p style="text-align: right;">Page 58</p> <p>1 and that's what is described here.  2 Q. When did you find out that he was an expert  3 for the defense in mold litigation?  4 A. After publication.  5 Q. Did you ever go back and make the  6 correction?  7 A. That he was a post-hoc expert?  8 Q. Yes.  9 A. No.  10 And so what then happened was --  11 Q. I didn't ask you what happened next.  12 A. You had asked --  13 I was answering the earlier question. You  14 don't want it?  15 Q. No. I -- I don't think your answer was  16 responsive to my question, so we'll move on.  17 You've -- you've been a faculty member for  18 the defense bar at various toxic tort seminars;  19 correct?  20 A. Once. I think once.  21 Q. Just once?  22 A. I gave a talk in March, I think, of this  23 year on the peer-review process in science at a  24 meeting of an organization that I had not heard of  25 before, but it was the defense bar, and I gave that</p>	<p style="text-align: right;">Page 60</p> <p>1 that describes associations between environmental  2 factors and health effects?  3 A. Yes, they can.  4 Q. You've opined that there is no causal  5 connection between benzene and multiple myeloma; is  6 that right?  7 A. Yes, I opined on that.  8 Q. Okay. And --  9 A. I think in that case I opined --  10 Q. I didn't ask --  11 I just wanted to know whether you did or  12 not.  13 MR. GORDON: Well Jan, I think you ought to  14 let him finish his answer.  15 MS. CONLIN: I've asked him simply "yes" or  16 "no" questions. I'm not going to waste my seven hours  17 with him giving me speaking testimony in questions I  18 didn't ask. You can -- you can ask him on followup.  19 MR. GORDON: Yeah. But it may be a "yes" --  20 what you think is a simple "yes" or "no" question, but  21 you -- you don't get to decide that.  22 Q. And more recently you've opined that there  23 is no specific causation relating to CS teargas or  24 causation relating to cleaning chemicals; correct?  25 A. That was a very specific case, and in that</p>

15 (Pages 57 to 60)

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<p style="text-align: right;">Page 61</p> <p>1 case I said that there was no evidence that the</p> <p>2 exposure to the cleaning agents caused the complaints</p> <p>3 of the person who was the claimant, but that the CS</p> <p>4 teargas clearly was the cause of symptoms.</p> <p>5 Q. Did --</p> <p>6 If we can take a look at your expert report,</p> <p>7 and I'd like to talk with you a little bit about -- I</p> <p>8 think it's on page --</p> <p>9 You listed in your report the four times</p> <p>10 that you have testified in the last few years, and for</p> <p>11 some reason I cannot seem to find that in what I've</p> <p>12 got.</p> <p>13 A. I think it was in an addendum. I don't</p> <p>14 think I listed it specifically --</p> <p>15 Q. Well let's see if I can --</p> <p>16 A. -- in the report.</p> <p>17 Q. Let's see if I can find it.</p> <p>18 Here, I got it.</p> <p>19 (Exhibit 6 was marked for</p> <p>20 identification.)</p> <p>21 BY MS. CONLIN:</p> <p>22 Q. I've handed you, sir, what's been marked as</p> <p>23 Borak Exhibit 6. Is this a list of your deposition</p> <p>24 and trial testimony between January 1st, 2013 and June</p> <p>25 1st, 2017?</p>	<p style="text-align: right;">Page 63</p> <p>1 between use of talc and ovarian cancer.</p> <p>2 A. I -- I wasn't asked that question. I was</p> <p>3 asked whether it had been opined and by whom and when,</p> <p>4 and I went through the literature, and I opined that</p> <p>5 it had not been said by anybody that it was a cause.</p> <p>6 Q. Were you --</p> <p>7 So your opinion was strictly that there</p> <p>8 was -- nothing in the literature provided a direct</p> <p>9 causal link between use of talc and ovarian cancer.</p> <p>10 A. I --</p> <p>11 You're paraphrasing what I said. I -- I</p> <p>12 said that a causal association had not been described</p> <p>13 in the literature and anywhere other than in court</p> <p>14 testimony.</p> <p>15 Q. Okay. Now in --</p> <p>16 You also testified in Stults versus American</p> <p>17 Popcorn Company in a deposition in 2013; correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And in that case you concluded that there is</p> <p>20 no causal link between diacetyl and what's known as</p> <p>21 popcorn lung; correct?</p> <p>22 A. No.</p> <p>23 Q. What was your testimony in that case?</p> <p>24 A. The testimony concerned the likelihood of a</p> <p>25 lung -- of bronchiolitis obliterans being caused in a</p>
<p style="text-align: right;">Page 62</p> <p>1 A. Yes, that's correct.</p> <p>2 Q. Aside from this deposition today, have you</p> <p>3 had your deposition taken in any other litigation</p> <p>4 between June 1st of this year and today?</p> <p>5 A. I -- I had a deposition taken on, I think,</p> <p>6 June 9.</p> <p>7 Q. Okay. What was the name of that case?</p> <p>8 A. I think the caption was Oules, O-u-l-e-s, v</p> <p>9 Johnson &amp; Johnson.</p> <p>10 Q. And what was the subject matter of your</p> <p>11 testimony in that case?</p> <p>12 A. The question I was asked to address was</p> <p>13 whether, when, and how it had been opined that talc</p> <p>14 caused ovarian cancer.</p> <p>15 Q. And you represent --</p> <p>16 Or your client in that case is Johnson &amp;</p> <p>17 Johnson?</p> <p>18 A. No.</p> <p>19 Q. The plaintiff?</p> <p>20 A. It is -- was a trade organization.</p> <p>21 Q. And in that case did you opine that there is</p> <p>22 no causal connection between talc and ovarian cancer?</p> <p>23 A. I -- I testified that the causation had not</p> <p>24 been proven.</p> <p>25 Q. That there wasn't a proven causal link</p>	<p style="text-align: right;">Page 64</p> <p>1 person who was a consumer of popcorn, and the</p> <p>2 individual himself had a significant underlying</p> <p>3 rheumatological disease which was the likely cause of</p> <p>4 his lung disease.</p> <p>5 Q. You found that exposure to diacetyl didn't</p> <p>6 cause the problems in the plaintiff in that case;</p> <p>7 correct?</p> <p>8 A. No, no, I didn't. The -- the problem --</p> <p>9 Your original question was whether I had</p> <p>10 opined that diacetyl did not cause the bronchiolitis</p> <p>11 obliterans, and I said no, that's not correct, I was</p> <p>12 not asked that opinion. And it is actually my opinion</p> <p>13 that under some circumstances diacetyl can cause the</p> <p>14 bronchiolitis obliterans.</p> <p>15 Q. But it didn't in this particular plaintiff.</p> <p>16 A. In this particular case, I don't believe</p> <p>17 that it did.</p> <p>18 Q. Okay. And what about In Re: World Trade</p> <p>19 Center, what was the subject matter of your testimony</p> <p>20 in that?</p> <p>21 A. The subject matter had to do with lung</p> <p>22 disease in somebody who had been a cleanup worker in</p> <p>23 buildings in the periphery of the World Trade Center.</p> <p>24 Q. Okay. And in that case you found that the</p> <p>25 exposure by the worker didn't cause the disease;</p>

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<p style="text-align: right;">Page 65</p> <p>1 correct?</p> <p>2 <b>A. It was my opinion that the man's cigarette</b></p> <p>3 <b>smoking and long history that predated the World Trade</b></p> <p>4 <b>Center explained his complaints.</b></p> <p>5 Q. Okay. And what was your -- subject matter</p> <p>6 of your testimony in Cabot Corporation?</p> <p>7 <b>A. I -- I already alluded to that. That had to</b></p> <p>8 <b>do with the adjudication in terms of the insurance</b></p> <p>9 <b>coverage for -- between two companies.</b></p> <p>10 Q. And what was the particular chemical of</p> <p>11 concern?</p> <p>12 <b>A. The issue had to do with if one could get</b></p> <p>13 <b>coal miner's pneumoconiosis in the absence of silica.</b></p> <p>14 Q. And in that case you concluded that the --</p> <p>15 that he can't; correct?</p> <p>16 (Discussion off the stenographic record.)</p> <p>17 <b>A. Yes. My conclusion was that the absence of</b></p> <p>18 <b>silica, that -- no, let me turn it the other way --</b></p> <p>19 <b>that the presence of silica contributed to the</b></p> <p>20 <b>formation of pneumoconiosis.</b></p> <p>21 Q. Okay. And how about in the final case,</p> <p>22 Secretary of Labor (MSHA) versus Klondex Midas, which</p> <p>23 side were you on in this case?</p> <p>24 <b>A. I -- I was involved with Klondex Midas, and</b></p> <p>25 <b>the case concerned whether medical causes of loss of</b></p>	<p style="text-align: right;">Page 67</p> <p>1 question.</p> <p>2 <b>A. I -- I don't object to his use of the</b></p> <p>3 <b>sufficient component cause model. I raise concerns at</b></p> <p>4 <b>the end of this section of my report and we could</b></p> <p>5 <b>address that specifically. Now it's not only the</b></p> <p>6 <b>conclusion, there was something in the method that I</b></p> <p>7 <b>had a problem with.</b></p> <p>8 Q. Okay. But the sufficient component</p> <p>9 causation methodology is well established and accepted</p> <p>10 amongst epidemiologists.</p> <p>11 <b>A. I -- I think probably. I -- I don't --</b></p> <p>12 <b>I'm not objecting to that.</b></p> <p>13 Q. Okay. And in fact you went through the same</p> <p>14 framework in connection with responding to Dr. Samet's</p> <p>15 report; correct?</p> <p>16 <b>A. Well I probably would have done that to be</b></p> <p>17 <b>responsive to Dr. Samet. I don't know if I would have</b></p> <p>18 <b>done it otherwise.</b></p> <p>19 Q. Okay. But you did in fact use the same</p> <p>20 framework. You didn't employ a different framework --</p> <p>21 <b>A. No. No.</b></p> <p>22 Q. -- in connection with responding; correct?</p> <p>23 <b>A. Yes, that's correct I think.</b></p> <p>24 Q. Okay. Would you agree with me that when</p> <p>25 you're looking at epidemiology, that drawing causal</p>
<p style="text-align: right;">Page 66</p> <p>1 <b>consciousness had been addressed and considered by a</b></p> <p>2 <b>coroner and others.</b></p> <p>3 Q. And what did you opine in that case?</p> <p>4 <b>A. I agreed with statements from the coroner</b></p> <p>5 <b>that she had not looked for such causes and could not</b></p> <p>6 <b>render such an opinion.</b></p> <p>7 Q. Now you talk in your expert report about</p> <p>8 sufficient component causation; correct?</p> <p>9 <b>A. Yes. I think I spoke to it in the context</b></p> <p>10 <b>of Dr. Samet's report.</b></p> <p>11 Q. Right. And you'd agree with me that it's a</p> <p>12 well accepted methodology in epidemiological studies;</p> <p>13 correct?</p> <p>14 <b>A. I accept the concept.</b></p> <p>15 Q. Yeah. And in fact it was first espoused by</p> <p>16 Dr. Rothman; correct?</p> <p>17 <b>A. I looked at it in Dr. Rothman's writings as</b></p> <p>18 <b>a result of Dr. Samet citing that, yes.</b></p> <p>19 Q. And you'd agree with me Dr. Rothman is one</p> <p>20 of the leading minds in epidemiology.</p> <p>21 <b>A. I think Dr. Rothman is a leading mind in</b></p> <p>22 <b>epidemiology.</b></p> <p>23 Q. So you don't take issue with Dr. Samet's</p> <p>24 methodology, just his conclusions; correct?</p> <p>25 MR. GORDON: Object to the form of the</p>	<p style="text-align: right;">Page 68</p> <p>1 inferences after finding association requires</p> <p>2 judgment?</p> <p>3 <b>A. Judgment is part of the requirements, yes.</b></p> <p>4 Q. Okay. Would you agree with me that although</p> <p>5 the drawing of causal inferences is informed by</p> <p>6 scientific expertise, it is not a determination that</p> <p>7 is made using an objective or algorithm -- algorithmic</p> <p>8 methodology?</p> <p>9 <b>A. It is not necessarily.</b></p> <p>10 Q. What do you mean by "it is not necessarily."</p> <p>11 <b>A. Well read me back your question and I'll</b></p> <p>12 <b>answer your second question. You asked me do I agree</b></p> <p>13 <b>that it is not, and I -- my answer was it was not</b></p> <p>14 <b>necessarily.</b></p> <p>15 Q. Okay. Would you agree, quote, "Although the</p> <p>16 drawing of a causal in" -- strike that. Let me start</p> <p>17 over.</p> <p>18 Would you agree with me, quote, "Although</p> <p>19 the drawing of causal inferences is informed by</p> <p>20 scientific expertise, it is not a determination that</p> <p>21 is made using an objective or algorithmic</p> <p>22 methodology," end quote?</p> <p>23 <b>A. Yes. It is not necessarily based upon such</b></p> <p>24 <b>an algorithmic approach.</b></p> <p>25 Q. Would you agree with me that, quote,</p>

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<p style="text-align: right;">Page 69</p> <p>1 "Deciding whether associations are causal is not a 2 matter of statistics but a matter of good scientific 3 judgment and the questions that should be asked with 4 respect to the data offered?"</p> <p>5 <b>A. In principle. But there are some terms in 6 that sentence which are difficult to define, such as 7 "good." "Good judgment" I think was the word.</b></p> <p>8 Q. Good scientific judgment.</p> <p>9 <b>A. Good scientific judgment. I don't know 10 quite what that means. But I can understand the 11 sentence.</b></p> <p>12 Q. Well would you agree with me that The 13 Reference Guide on Statistics authored by Drs. Kay and 14 Friedman is an authoritative work?</p> <p>15 <b>A. It's a reference that I refer to.</b></p> <p>16 Q. Okay. And you rely on it; right?</p> <p>17 <b>A. I do.</b></p> <p>18 Q. And you don't take issue with what Drs. Kay 19 and Friedman have written in connection with The 20 Reference Guide on Statistics. In fact, you've relied 21 on it; correct?</p> <p>22 <b>A. That's correct.</b></p> <p>23 Q. I'd like to direct your attention, sir, to 24 paragraph -- or page three of your expert report in 25 this case, Borak Exhibit No. 1. Do you have that in</p>	<p style="text-align: right;">Page 71</p> <p>1 of SSI."</p> <p>2 <b>A. Yes, I said that.</b></p> <p>3 Q. Okay. I take it that you think the CDC in 4 terms of --</p> <p>5 You know, let me strike that and ask it a 6 different way.</p> <p>7 You relied on the CDC guidelines here in 8 connection with your report; correct?</p> <p>9 <b>A. I -- I cited it, yes.</b></p> <p>10 Q. Okay. And you relied on it.</p> <p>11 <b>A. Well I relied upon it as an example of a 12 statement from a well-regarded organization, yes.</b></p> <p>13 Q. Okay. And you agree the CDC is well- 14 regarded; correct?</p> <p>15 <b>A. Generally, yes.</b></p> <p>16 Q. Okay. In connection with your work over the 17 course of your career, your emphasis has been on 18 exposure to environmental toxins as opposed to 19 infectious agents; correct?</p> <p>20 <b>A. For the most part.</b></p> <p>21 Q. Have you ever opined in a case that involved 22 not an environmental toxin but an infectious agent?</p> <p>23 <b>A. Years ago, when I ran a trauma center, I was 24 involved in litigation that involved malpractice kinds 25 of issues, clinical malpractice issues, and I can</b></p>
<p style="text-align: right;">Page 70</p> <p>1 front of you?</p> <p>2 <b>A. I do.</b></p> <p>3 Q. Okay. And I'd like to direct your attention 4 to Roman No. II, "The Samet Report." In 11a you talk 5 about this notion that there is sufficient evidence 6 that warming surgical patients to prevent hypothermia 7 and maintain normothermia reduces the rates of SSI; 8 correct?</p> <p>9 <b>A. Correct.</b></p> <p>10 Q. And you cite to the CDC's guideline as one 11 of your references; correct?</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. And the World Health Organization; correct?</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. Okay. Did you investigate what -- what 16 information either the CDC or WHO had in connection 17 with their suggestion and determination that warming 18 is important?</p> <p>19 <b>A. Well I -- I've read the documents and I've 20 looked at some of the references. Is that an answer 21 to your question?</b></p> <p>22 Q. Okay. And you say in the next paragraph, 23 "In addition, published findings from two random 24 control trials document that use of Bair Hugger to 25 maintain intraoperative normothermia reduced the risk</p>	<p style="text-align: right;">Page 72</p> <p>1 <b>remember in that context there were questions that 2 arose regarding infections. But that would have been 3 some time ago.</b></p> <p>4 Q. Well you were a participant. It was part 5 of --</p> <p>6 I mean you were involved in that case as a 7 result of your work; correct?</p> <p>8 <b>A. No, no. I was an expert in that context.</b></p> <p>9 Q. When was that?</p> <p>10 <b>A. Oh, it --</b></p> <p>11 <b>There were more than one, and it would have 12 been before 1990 because before -- in 1990 I 13 essentially separated myself from my emergency 14 practice, and during the time between 1980 and 1990, 15 approximately, I was involved in a fairly large number 16 of litigation questions, often only from the 17 standpoint of looking at medical records and saying 18 whether I thought there was or was not some kind of a 19 problem, and in that context, some of those involved 20 infectious diseases.</b></p> <p>21 Q. Have you ever been retained, litigation or 22 non-litigation, to provide an epidemiological opinion 23 that relates to an infectious organism?</p> <p>24 <b>A. I did some work several years ago at the 25 interface of epidemiology and occupational medicine</b></p>

18 (Pages 69 to 72)



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<p style="text-align: right;">Page 73</p> <p>1 and public health, and it was during the Ebola 2 outbreak, and it had to do with the development of 3 occupational protocols for workplaces to minimize the 4 risk of spread of that infectious disease. The 5 particular issue involved some companies that operated 6 mines in the Caribbean who had workers, many of whom 7 went back and forth to Africa at the time. I recall 8 as well being involved in the development of 9 influenza-related policies for workplaces, 10 white-collar workplaces, at a time when either SARs or 11 influenza was of great concern. So those are two 12 examples.</p> <p>13 Q. Okay. My question was a little different. 14 Have you ever undertaken an epidemiologic study that 15 relates to looking at causation issues of an 16 infectious organism?</p> <p>17 A. Oh, that's a different question. I think 18 the answer is probably no.</p> <p>19 Q. Now if we look at the paragraph we were 20 looking at, you say, "In addition, published findings 21 from two random control trials document that use of 22 Bair Hugger to maintain intraoperative normothermia 23 reduced the risk of SSI," and you list references 24 three and four. And if we look at your reference 25 list, that refers to a paper by Kurz and Sessler as</p>	<p style="text-align: right;">Page 75</p> <p>1 it's important when you're undertaking an 2 epidemiologic study, particularly one that relates to 3 association or causation, to have all the information. 4 Did you ask for all the information that might be 5 pertinent to your decision?</p> <p>6 MR. GORDON: Object to the form of the 7 question.</p> <p>8 A. I -- I don't know that there even is such 9 information to have asked for.</p> <p>10 Q. Well did you tell Mr. Gordon, the lawyer for 11 3M, "If I'm going to undertake this, I want to look at 12 all the evidence that's been accumulated by the 13 parties in this case?"</p> <p>14 A. I --</p> <p>15 It was understood that I could ask for 16 whatever I thought I needed. I didn't know that there 17 was ever a question of those two articles. They've 18 been cited repeatedly. I've never seen them 19 retracted. The index of the National Library of 20 Medicine does not indicate that they have been 21 qualified, so it's not my understanding that I was 22 citing here problematic papers, and I don't think I 23 have any reason to know that they were reviewed by 24 anybody as problematic.</p> <p>25 Q. But you didn't ask the question. Did you --</p>
<p style="text-align: right;">Page 74</p> <p>1 well as Melling; correct?</p> <p>2 A. That's correct.</p> <p>3 Q. Okay. Did you look at the depositions that 4 were taken by Dr. Kurz and Sessler in this case?</p> <p>5 A. I -- I don't think so. Let me -- 6 Dr. Kurz and Dr. Melling?</p> <p>7 Q. Well one paper was --</p> <p>8 A. You -- you asked me about --</p> <p>9 Q. -- Kurz and Sessler. My question was: Did 10 you look at their depositions in this case?</p> <p>11 A. The answer is no, I don't believe so. I 12 don't see them on my list.</p> <p>13 Q. Were you aware or told that Dr. Kurz 14 disavowed both the study in which she was an author as 15 well as the Melling -- Melling study?</p> <p>16 MR. GORDON: Object to the form of the 17 question, completely misstates her testimony.</p> <p>18 A. I -- I'm not aware that either one was 19 deposed.</p> <p>20 Q. Don't you think that that would be important 21 to know when you're relying on things such as these 22 two studies?</p> <p>23 MR. GORDON: Same objection.</p> <p>24 A. I -- I don't have any information about it.</p> <p>25 Q. Well you testified previously that you think</p>	<p style="text-align: right;">Page 76</p> <p>1 Did you ever say to the lawyers for 3M, "I'd 2 like to know all the depositions that have been taken 3 in this case?"</p> <p>4 A. No.</p> <p>5 Q. Or "I would like to see any evidence that 6 might exist that undercuts what I'm writing in my 7 report?"</p> <p>8 A. I was writing a -- a report and I thought I 9 had much of the information. If you're telling me 10 that there's important information that I don't have, 11 I would be interested to know.</p> <p>12 (Exhibit 7 was marked for 13 identification.)</p> <p>14 BY MS. CONLIN:</p> <p>15 Q. I've handed you, sir, what's been marked as 16 Borak Deposition Exhibit No. 7, which is the 17 deposition of Andrea Kurz dated January 12th, 2017, 18 and you'll see that on that first page, internal page 19 four, it lists Mr. Gordon, the lawyer sitting next to 20 you, present at the deposition, as well as a Mr. 21 Assaad.</p> <p>22 Have you seen this before?</p> <p>23 A. I don't believe I have.</p> <p>24 Q. Okay. Okay. If you can take a look at page 25 one seven -- internal page 177, which is the last page</p>

19 (Pages 73 to 76)



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<p>1 of this document, --</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. -- and they're talking there about the study</p> <p>4 which you've listed as reference number three, and she</p> <p>5 says at the top of the page:</p> <p>6 "...it's a retrospective study and not one</p> <p>7 of the best-done either. So you --</p> <p>8 "Question: Based on in today's standards.</p> <p>9 "Answer: Based on in today's standards.</p> <p>10 "Okay. It might have been good standards</p> <p>11 back in 1996."</p> <p>12 Then it says, "Okay. And Dr. Sessler has</p> <p>13 mentioned in an e-mail before, in today's standards</p> <p>14 and with respect to reliability of studies, that he</p> <p>15 probably wouldn't have published the 1996 Kurz paper.</p> <p>16 Do you agree with him?</p> <p>17 "Absolutely.</p> <p>18 "Okay.</p> <p>19 "I would not have either."</p> <p>20 And if you look down at the bottom of page</p> <p>21 178 with reference to the Melling study, "It was an</p> <p>22 okay study for" --</p> <p>23 Starting -- page 178, starting at line 16:</p> <p>24 "Question: Do you think Melling was a good</p> <p>25 study?</p>	<p>1 opinion on whether the use of Bair Hugger increases</p> <p>2 the number of particulates over a surgical site?</p> <p>3 <b>A. I -- I don't have such an opinion.</b></p> <p>4 Q. One way or another.</p> <p>5 <b>A. One way or another.</b></p> <p>6 Q. Okay. Have you done any investigation into</p> <p>7 that issue?</p> <p>8 <b>A. I -- I have read a number of papers, but it</b></p> <p>9 <b>is not my area of expertise, and I read them only</b></p> <p>10 <b>because occasionally -- they've occasionally been</b></p> <p>11 <b>cited by some of the others in this case.</b></p> <p>12 Q. Okay. Do you think that, in connection with</p> <p>13 reaching a conclusion, which you did, that there is no</p> <p>14 association between the use of Bair Hugger and a risk</p> <p>15 of infection, that it would be important to ascertain</p> <p>16 whether use of the Bair Hugger increases the number of</p> <p>17 particulates over the surgical site?</p> <p>18 <b>A. I -- I rendered my opinion on the basis of</b></p> <p>19 <b>my understanding of evidence linking Bair Hugger and</b></p> <p>20 <b>infection, not based upon Bair Hugger and particulates</b></p> <p>21 <b>per se.</b></p> <p>22 Q. So you haven't done any investigation, for</p> <p>23 example, into the paper -- published papers by Stocks</p> <p>24 or Darouiche as whether increased particulates over a</p> <p>25 surgical site can increase the risk of infection.</p>
Page 78	Page 80
<p>1 "Answer: It was an okay study for the time.</p> <p>2 "Question: Would you agree with me that it</p> <p>3 wouldn't be publishable today?</p> <p>4 "Answer: I absolutely would agree with</p> <p>5 you."</p> <p>6 <b>A. You seem to have read it correctly.</b></p> <p>7 Q. Okay. And if you look at the top of page</p> <p>8 179, question at line 16:</p> <p>9 "In today's scientific standards, there is</p> <p>10 no reliable evidence that supports that maintaining</p> <p>11 normothermia reduces the incidence of infection.</p> <p>12 "Answer: That is correct."</p> <p>13 Were you aware of that testimony before</p> <p>14 today?</p> <p>15 <b>A. No, I was not.</b></p> <p>16 Q. Did you do any investigation into the</p> <p>17 Sessler -- or the Kurz/Sessler and Melling papers as</p> <p>18 part of your opinions in this case?</p> <p>19 <b>A. I did not.</b></p> <p>20 Q. Do you have an opinion on whether the use of</p> <p>21 Bair Hugger increases the number of particulates over</p> <p>22 a surgical site?</p> <p>23 <b>A. I have seen papers that suggest it does and</b></p> <p>24 <b>I have seen papers that suggest it might not.</b></p> <p>25 Q. My question was different. Do you have an</p>	<p>1 <b>A. I have read both of those papers. I have no</b></p> <p>2 <b>expert opinions about the question you ask.</b></p> <p>3 Q. Okay. And you don't cite to or rely on</p> <p>4 Darouiche or Stocks in connection with your</p> <p>5 conclusions that are rendered in your -- or contained</p> <p>6 in your June 2nd expert report.</p> <p>7 <b>A. Yes, that is correct. It was my opinion</b></p> <p>8 <b>that it was the link between the use of Bair Hugger</b></p> <p>9 <b>and the evidence of infection that mattered.</b></p> <p>10 Q. Okay. But you also understand as an</p> <p>11 epidem -- as someone studying epidemiology that you</p> <p>12 have to look at the chain of infection; right?</p> <p>13 There's a concept is called biological plausibility;</p> <p>14 correct?</p> <p>15 <b>A. Well I --</b></p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 <b>A. I -- I understand that there is such an</b></p> <p>19 <b>issue of plausibility and potentiality, yes.</b></p> <p>20 Q. Okay. And you didn't think it was important</p> <p>21 to understand whether, by way of mechanism, the Bair</p> <p>22 Hugger would increase the number of particulates over</p> <p>23 the surgical site?</p> <p>24 <b>A. I -- I understood the argument that there</b></p> <p>25 <b>might be such a mechanism. I opined, based upon the</b></p>

20 (Pages 77 to 80)

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<p style="text-align: right;">Page 81</p> <p>1 evidence, that there was a link between Bair Hugger 2 and infections, not on whether there was some 3 intermediary process that might be linked. 4 Q. Well how do you understand how the Bair 5 Hugger might increase the risk of infection? 6 A. I understand that there are theoretical 7 mechanisms that might be at play, and I would frankly 8 defer that to Dr. Wenzel. I was not asked to opine 9 about the theoretical mechanisms and I have not opined 10 about them. 11 Q. So your opinion that there is no association 12 between Bair Hugger and risk of infection is divorced 13 from a concept of whether it increases particulates 14 over the surgical site. 15 MR. GORDON: Object to the form of the 16 question. 17 A. I -- I -- there -- 18 There are two parts of an answer. The first 19 one is that you misdescribe my opinion, and the second 20 is that I -- my opinion was not dependent upon whether 21 there was or wasn't a change in the particulate load. 22 Q. Okay. And so if there was a substantial 23 increase of particulates over the surgical site caused 24 by the Bair Hugger, that would not inform your opinion 25 one way or another.</p>	<p style="text-align: right;">Page 83</p> <p>1 would not inform your opinion one way or the other. 2 A. It would inform thinking about a 3 hypothetical association. In the absence of evidence 4 linking Bair Hugger and surgical infections, the 5 presence of particulates, as you describe them, would 6 be interesting but insufficient to point to causation. 7 Q. Okay. I wasn't asking you about causation, 8 but -- 9 Do you have an opinion of whether an 10 increased number of particles over a surgical site 11 creates an increased risk of infection? 12 A. I don't have such an opinion. I am not an 13 expert in that domain. I understand the logic of it, 14 but it's not an area that I know well enough to opine. 15 Q. You talk about SSIs or surgical-site 16 infections throughout your report. Could you give me 17 a definition of that? 18 A. In the context, I was looking specifically 19 at infections following -- I -- I principally was 20 thinking about infections following arthroplastic 21 surgery, and my intent was to speak to deep 22 infections, but I think in some places I may have used 23 the term more generally to speak of infections at 24 surgical sites. 25 Q. Okay. So where I see "SSI" in your report,</p>
<p style="text-align: right;">Page 82</p> <p>1 A. I -- I -- I think I described that in my 2 report, and I can turn to it if you like. It had to 3 do with the end of my discussion of causality, and I 4 said that in the absence of evidence -- 5 I perhaps should look at it so I don't badly 6 paraphrase it, if you don't mind. 7 Q. Sure. I think you're on page 21, paragraphs 8 68 and 69. 9 A. You know it better than I do. I'm 10 impressed. Thank you. If others would read my work 11 as well as you do, I would be flattered. 12 In paragraph 71 I wrote, "In the absence of 13 valid evidence of a causal association between Bair 14 Hugger and SSI, it can only be said that the 15 mechanistic studies are coherent with a hypothetical 16 increase in SSI." And "Hypothetical associations," I 17 believe, "are not sufficient to sustain an inference 18 of causation." 19 Q. Okay. 20 A. I think that's what you were asking me 21 about. 22 Q. Not necessarily. 23 My question is: And so if there was a 24 substantial increase in the number of particulates 25 over the surgical site caused by the Bair Hugger, that</p>	<p style="text-align: right;">Page 84</p> <p>1 you really meant deep joint infection? 2 A. If you point to them, I'll try to clarify. 3 Q. Well -- 4 A. I may have used it ambiguously. 5 Q. Okay. Do you understand the difference 6 between a -- what's known to doctors as a deep 7 incisional infection and a deep joint infection? 8 A. I -- 9 MR. GORDON: Object to the form of the 10 question. 11 A. I think I do, but maybe you will clarify. 12 Q. Okay. What's your understanding? 13 A. I think that a deep infection of a wound, if 14 we're talking about non-arthroplastic, it's not in the 15 joint, it's not orthopedic, and is in the deeper 16 tissues of the surgical area; and a joint infection 17 seems to be fairly straightforward, it is in the area 18 of the joint. 19 Q. Do you know how -- 20 Did you do any investigation as to how deep 21 joint infections occur? 22 A. Not per se. 23 Q. Do you have any understanding of bio -- the 24 term "biofilm" as it relates to infectious organisms 25 on prosthetic joints?</p>

21 (Pages 81 to 84)

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<p>1 <b>A. I have read about bio -- biofilms.</b></p> <p>2 Q. Have you done any investigation into whether</p> <p>3 or not antibiotics are effective in connection with a</p> <p>4 biofilm formed on a prosthetic?</p> <p>5 <b>A. It is my understanding that biofilms can</b></p> <p>6 <b>make antibiotics less effective.</b></p> <p>7 Q. My question was: Did you do any</p> <p>8 investigation into that?</p> <p>9 <b>A. I -- I read about that.</b></p> <p>10 Q. Okay. But you didn't undertake an</p> <p>11 exhaustive literature review in connection with that.</p> <p>12 <b>A. I -- I -- I did not do an exhaustive</b></p> <p>13 <b>literature review. My understanding was that Dr.</b></p> <p>14 <b>Wenzel would do that.</b></p> <p>15 Q. Okay. Did you meet with Dr. Wenzel other</p> <p>16 than this meeting in DC on May 8th?</p> <p>17 <b>A. No, we've never met since then.</b></p> <p>18 Q. Okay. How long did the meeting go?</p> <p>19 <b>A. I would guess three or four hours, but I'm</b></p> <p>20 <b>not sure.</b></p> <p>21 Q. Have you spoken to him since then?</p> <p>22 <b>A. I think I spoke to him once.</b></p> <p>23 Q. What was that in connection with?</p> <p>24 <b>A. I think I was asking him a question about a</b></p> <p>25 <b>definition of surgical infections.</b></p>	<p>1 Have you met Mr. Van Duren before?</p> <p>2 <b>A. No.</b></p> <p>3 Q. Have you met a single individual at 3M in</p> <p>4 connection with your work in this case?</p> <p>5 MR. GORDON: Non-lawyers you mean.</p> <p>6 <b>A. Yeah. I met a Mr. Boone when you and I</b></p> <p>7 <b>first met about a week ago, and I understood he was</b></p> <p>8 <b>in -- in -- inside at 3M. But other than that, no, I</b></p> <p>9 <b>don't think so.</b></p> <p>10 Q. You never talked with any of the folks that</p> <p>11 are involved with Bair Hugger at 3M.</p> <p>12 <b>A. Not that I'm aware of.</b></p> <p>13 Q. Okay. And certainly not in connection with</p> <p>14 the opinions you rendered in this case.</p> <p>15 <b>A. I don't think so.</b></p> <p>16 Q. Okay. If we can take a look on the back</p> <p>17 page of what's been previously marked as Holford</p> <p>18 Deposition Exhibit 11, and if you can direct your</p> <p>19 attention to the internal page 258, starting on line</p> <p>20 five, where the corporate representative for 3M was</p> <p>21 asked the following question:</p> <p>22 "Okay. Based on the data we have today,</p> <p>23 including the study funded by 3M as well as other</p> <p>24 studies, every single study indicates that Bair Hugger</p> <p>25 increases the particle count over the sterile field.</p>
Page 86	Page 88
<p>1 Q. What did he tell you?</p> <p>2 <b>A. I don't recall his answer. I'm sorry.</b></p> <p>3 Q. Did you see his report before it went in?</p> <p>4 <b>A. I think I did, yes.</b></p> <p>5 Q. You haven't looked at any of the expert</p> <p>6 reports that have been proffered either by 3M or the</p> <p>7 plaintiffs in connection with computational fluid</p> <p>8 dynamics?</p> <p>9 <b>A. Yes, I have not looked at those reports.</b></p> <p>10 Q. Okay. Were you aware that corporate</p> <p>11 representatives for 3M have testified in this case</p> <p>12 that the use of the Bair Hugger increases the number</p> <p>13 of particles over the surgical site?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 <b>A. I -- I don't think I'm aware of that. Maybe</b></p> <p>17 <b>I heard it. I don't know. I haven't read it.</b></p> <p>18 MS. CONLIN: If we could pull out Exhibit 11</p> <p>19 from yesterday, Mr. Stirewalt.</p> <p>20 (Holford Exhibit 11 handed to the witness.)</p> <p>21 THE WITNESS: Thank you.</p> <p>22 Q. I've handed you what was marked during</p> <p>23 Professor Holford's deposition as Exhibit 11, which is</p> <p>24 an excerpt out of the 30(b)(6) deposition of Al Van</p> <p>25 Duren.</p>	<p>1 "Answer: In absolute numbers, yes.</p> <p>2 "Question: Yes. Okay. And you have no</p> <p>3 internal studies to refute that?</p> <p>4 "No, we don't."</p> <p>5 Do you see that?</p> <p>6 <b>A. I do see that.</b></p> <p>7 Q. Okay. Did you ever investigate why 3M would</p> <p>8 be concerned about increased particulates over the</p> <p>9 sterile surgical site?</p> <p>10 <b>A. I did not --</b></p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question, assumes facts not evidence.</p> <p>13 MS. CONLIN: You may answer.</p> <p>14 <b>A. I did not investigate that.</b></p> <p>15 Q. Okay. I take it it's because you didn't</p> <p>16 think it was important to the conclusions that you</p> <p>17 rendered; correct?</p> <p>18 <b>A. I didn't know that it had been done.</b></p> <p>19 Q. Well now that you know it had been done, is</p> <p>20 that information you thought you should have had in</p> <p>21 connection with your opinions?</p> <p>22 <b>A. I had determined early in this process,</b></p> <p>23 <b>probably going back to that meeting in May, that I was</b></p> <p>24 <b>not going to be dealing with the issue of particles,</b></p> <p>25 <b>as you're describing them.</b></p>

22 (Pages 85 to 88)

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<p style="text-align: right;">Page 89</p> <p>1 Q. And you didn't think that was important to</p> <p>2 look at in connection with the opinions that you've</p> <p>3 rendered; correct?</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question.</p> <p>6 <b>A. Yes. In the absence of evidence that Bair</b></p> <p>7 <b>Hugger caused joint infections, I did not think that</b></p> <p>8 <b>the particle information mattered.</b></p> <p>9 Q. Why didn't it matter?</p> <p>10 <b>A. Because infections were what mattered.</b></p> <p>11 Q. Well, do you know whether -- you --</p> <p>12 You understand that both Darouiche and</p> <p>13 Stocks and others have said that an increase of</p> <p>14 particulates equals -- or can equal an increase in the</p> <p>15 number of infectious organisms; correct?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 <b>A. I -- I have read some who have said that,</b></p> <p>19 <b>and I have read others who apparently found no</b></p> <p>20 <b>evidence of either increased particulates or bacteria,</b></p> <p>21 <b>and I have read others who found no evidence of</b></p> <p>22 <b>bacteria at all. I have not rendered an opinion on</b></p> <p>23 <b>that particular body of literature.</b></p> <p>24 Q. You have no opinion on whether an increase</p> <p>25 in particulates over a surgical site can increase the</p>	<p style="text-align: right;">Page 91</p> <p>1 in the air. They are so sensitive to this issue that</p> <p>2 they discussed the contribution of talking to</p> <p>3 particulates, and to the difference in squames</p> <p>4 shedding between male and female OR staff. They</p> <p>5 equate particulates with bacteria in the air and cite</p> <p>6 studies (do not have the citations) that support</p> <p>7 this." Do you see that?</p> <p>8 <b>A. I've read that, yes.</b></p> <p>9 Q. Okay. And did you read this today for the</p> <p>10 first time?</p> <p>11 <b>A. Yes, that's correct.</b></p> <p>12 Q. This isn't a document that you saw in</p> <p>13 connection with your expert opinions in this case?</p> <p>14 <b>A. I've never seen this before.</b></p> <p>15 Q. Do you think it would be important if the</p> <p>16 people who are selling the Bair Hugger are concerned</p> <p>17 that par -- there's an equation of particulates with</p> <p>18 bacteria in the air --</p> <p>19 MR. GORDON: Object --</p> <p>20 Q. -- and that they've cited to studies that</p> <p>21 support this?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, miscon -- misconstrues the document and the</p> <p>24 evidence.</p> <p>25 <b>A. I -- I can understand the concern that this</b></p>
<p style="text-align: right;">Page 90</p> <p>1 risk of infection.</p> <p>2 <b>A. I think it would matter greatly what kind of</b></p> <p>3 <b>particulates. There are all kinds of issues there</b></p> <p>4 <b>that I do not know with sufficient expertise.</b></p> <p>5 <b>(Exhibit 8 was marked for</b></p> <p>6 <b>identification.)</b></p> <p>7 THE WITNESS: Thank you.</p> <p>8 BY MS. CONLIN:</p> <p>9 Q. I have handed you, sir, what's been marked</p> <p>10 as Borak Exhibit 8, which is an e-mail from Michelle</p> <p>11 Hulse Stevens at 3M to a number of people at 3M.</p> <p>12 You've never met Dr. Hulse Stevens before?</p> <p>13 <b>A. No.</b></p> <p>14 Q. Okay. And you see the subject is "FAW" --</p> <p>15 which is forced-air warming -- "aerobiology and the</p> <p>16 Orthopedic International Consensus Meeting on</p> <p>17 Prevention of Prosthetic Joint Infection." Do you see</p> <p>18 that?</p> <p>19 <b>A. I do see that.</b></p> <p>20 Q. Okay. And she starts by saying, "All,</p> <p>21 "I sat in on the group addressing the OR</p> <p>22 environment to this consensus document. There is</p> <p>23 amazing concern about any particulates in the air</p> <p>24 during joint replacement surgery and almost uniform</p> <p>25 comment that forced-air warming increases particulates</p>	<p style="text-align: right;">Page 92</p> <p>1 <b>panel would have raised.</b></p> <p>2 Q. Do you think it would be important if the</p> <p>3 people who are selling the Bair Hugger were concerned</p> <p>4 about it creating an increase of particulates in the</p> <p>5 air over the surgical site?</p> <p>6 <b>A. It may have been a very appropriate thing</b></p> <p>7 <b>for them to be concerned about.</b></p> <p>8 Q. But you didn't know that they were until</p> <p>9 today; correct?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question, it assumes facts not in evidence, mis -- and</p> <p>12 misconstrues the evidence.</p> <p>13 <b>A. I've never seen this document before.</b></p> <p>14 Q. Okay. In your report you express no opinion</p> <p>15 on whether the Bair Hugger can create convective</p> <p>16 turbulence in the OR; correct?</p> <p>17 <b>A. I rendered no such opinions.</b></p> <p>18 Q. Okay. And you haven't looked at any</p> <p>19 literature aside from McGovern that addresses that</p> <p>20 specific subject.</p> <p>21 <b>A. I -- I -- I have read articles about it, but</b></p> <p>22 <b>I have no opinion about it and I've rendered no</b></p> <p>23 <b>opinion about it.</b></p> <p>24 Q. And I take it you didn't think that that was</p> <p>25 important in connection with the opinions that you've</p>

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<p style="text-align: right;">Page 93</p> <p>1 expressed in your expert report.</p> <p>2 <b>A. As I've explained, I thought that the link</b></p> <p>3 <b>between Bair Hugger and surgical-site infections was</b></p> <p>4 <b>the critical issue, and that's what I focused on.</b></p> <p>5 Q. But you didn't, in connection with that</p> <p>6 link, you didn't look at or investigate whether the</p> <p>7 use of the Bair Hugger can create particulates that</p> <p>8 can create that link.</p> <p>9 <b>A. I -- I read that there was literature which</b></p> <p>10 <b>addressed that, and I understood that others were</b></p> <p>11 <b>going to address that.</b></p> <p>12 Q. So I take it if someone said there was a</p> <p>13 risk of airborne contamination with the Bair Hugger,</p> <p>14 you'd disagree with that.</p> <p>15 <b>A. No. I don't have enough evidence to say</b></p> <p>16 <b>that. I would say that there is no good evidence that</b></p> <p>17 <b>use of the Bair Hugger causes surgical-site</b></p> <p>18 <b>infections.</b></p> <p>19 Q. Well would you -- if --</p> <p>20 If someone said that there's a risk of</p> <p>21 airborne contamination with the Bair Hugger, would</p> <p>22 that be of import to you or not?</p> <p>23 <b>A. It's of interest to me.</b></p> <p>24 Q. Okay. But you haven't seen anything that</p> <p>25 says that; right?</p>	<p style="text-align: right;">Page 95</p> <p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 <b>A. I'm accepting that what you've read is</b></p> <p>4 <b>correct. I don't see it here, but that doesn't, I</b></p> <p>5 <b>think, matter.</b></p> <p>6 Q. Well take a look at the last sentence under</p> <p>7 "SAFETY." Do you see it says --</p> <p>8 <b>A. Ah, yes. Okay. There I see it.</b></p> <p>9 Q. -- "The predicate device..."</p> <p>10 <b>A. Okay. Thank you.</b></p> <p>11 Q. Okay?</p> <p>12 <b>A. So what you're saying is this is a request</b></p> <p>13 <b>for a subsequent machine to be adopted based upon the</b></p> <p>14 <b>history of that predecessor, the predicate.</b></p> <p>15 Q. Right.</p> <p>16 <b>A. Okay.</b></p> <p>17 Q. Okay? And you see on the first page it</p> <p>18 talks about "Summary of Safety;" correct?</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. Okay. And I'd like to direct your attention</p> <p>21 to the back page of this exhibit. Do you see section</p> <p>22 C. "Other Safety Concerns:</p> <p>23 "1. Contamination. Airborne contamination</p> <p>24 from air blown intraoperatively across the surgical</p> <p>25 wound may result in airborne contamination."</p>
<p style="text-align: right;">Page 94</p> <p>1 <b>A. I have seen papers that have indicated that</b></p> <p>2 <b>there were increased particulates and I have read</b></p> <p>3 <b>papers that said that there weren't.</b></p> <p>4 <b>(Discussion off the stenographic record.)</b></p> <p>5 <b>(Exhibit 9 was marked for</b></p> <p>6 <b>identification.)</b></p> <p>7 BY MS. CONLIN:</p> <p>8 Q. I've handed you, sir, what's been marked as</p> <p>9 Borak Exhibit 9, which is a 510(k) summary of safety</p> <p>10 and effectiveness dated January 10th, 1996 involving</p> <p>11 FDA approval of the Bair Hugger 750.</p> <p>12 Do you have any understanding of the</p> <p>13 differences in designs between, for example, the 500</p> <p>14 or the 750?</p> <p>15 <b>A. I've seen reference to it, but I don't know</b></p> <p>16 <b>what the differences are. And I don't know what a</b></p> <p>17 <b>510(k) is.</b></p> <p>18 Q. 510(k) is when you are seeking abbreviated</p> <p>19 approval through the FDA based on a predicate device.</p> <p>20 <b>A. Okay.</b></p> <p>21 Q. So if you look at the first paragraph here,</p> <p>22 it will say, last sentence under "SAFETY," "The</p> <p>23 predicate device is the Bair Hugger Patient Warming</p> <p>24 System, Model 500 Warming Unit." Okay?</p> <p>25 <b>A. I --</b></p>	<p style="text-align: right;">Page 96</p> <p>1 Do you see that?</p> <p>2 <b>A. I do.</b></p> <p>3 Q. Okay. Now this was submitted in connection</p> <p>4 with the Bair Hugger model 750. Have you ever seen</p> <p>5 this before?</p> <p>6 <b>A. No.</b></p> <p>7 Q. Okay. Would this be something that you</p> <p>8 would view as important in connection with the</p> <p>9 conclusions contained in your expert report in this</p> <p>10 case?</p> <p>11 <b>A. As I've explained, my expert opinion was</b></p> <p>12 <b>based upon what I found as evidence linking Bair</b></p> <p>13 <b>Hugger with infections. So this is interesting, but</b></p> <p>14 <b>this is not evidence of infections.</b></p> <p>15 Q. Well you understand that the mechanism of</p> <p>16 infections is through airborne contamination;</p> <p>17 correct, --</p> <p>18 MR. GORDON: Object --</p> <p>19 Q. -- sir?</p> <p>20 MR. GORDON: Object to the form of the</p> <p>21 question, assumes facts not in evidence.</p> <p>22 <b>A. I understand that that is an area that Dr.</b></p> <p>23 <b>Wenzel is going to be opining about, that I was not</b></p> <p>24 <b>going to opine about that, and so I have no opinion</b></p> <p>25 <b>about that.</b></p>

24 (Pages 93 to 96)



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<p style="text-align: right;">Page 97</p> <p>1 Q. Well you understand when --</p> <p>2 When you've opined that there is no</p> <p>3 association between the use of the Bair Hugger and</p> <p>4 infection, you understand the mechanism by which</p> <p>5 plaintiffs are alleging the infection occurs is</p> <p>6 through airborne contamination; correct?</p> <p>7 <b>A. Well once again you have asked a question</b></p> <p>8 <b>which has two different parts of it. First of all, I</b></p> <p>9 <b>do not accept your description of my opinion.</b></p> <p>10 <b>Secondly, I'm not sure what the plaintiffs are</b></p> <p>11 <b>alleging. I understand there was discussion of the</b></p> <p>12 <b>airborne particulates as being a possible intermediary</b></p> <p>13 <b>in the development of infection. I have been looking</b></p> <p>14 <b>at the infections.</b></p> <p>15 Q. Okay. And so you did no analysis as to</p> <p>16 whether the Bair Hugger can create airborne</p> <p>17 contamination; correct?</p> <p>18 <b>A. I think I've explained that I was not asked</b></p> <p>19 <b>and agreed that I would not be addressing and did not</b></p> <p>20 <b>do an investigation to determine whether that was so.</b></p> <p>21 Q. Well how can you find that there is no</p> <p>22 association between Bair Hugger and infections if you</p> <p>23 didn't investigate the mechanism by which those</p> <p>24 infections can occur?</p> <p>25 MR. GORDON: Object to the form of the</p>	<p style="text-align: right;">Page 99</p> <p>1 infection?</p> <p>2 <b>A. And the answer was I read articles and</b></p> <p>3 <b>reports that were relevant to the question, but I did</b></p> <p>4 <b>not render an opinion, and I do not have one to offer</b></p> <p>5 <b>you now as to whether Bair Hugger causes -- and your</b></p> <p>6 <b>phrase was --</b></p> <p>7 Q. Create airborne contamination which can lead</p> <p>8 to infection.</p> <p>9 <b>A. Yes. I do not have an opinion as to whether</b></p> <p>10 <b>it does that because it is my opinion that there is</b></p> <p>11 <b>not sufficient evidence that it causes infection.</b></p> <p>12 Q. Well if you didn't look at the issue of</p> <p>13 whether it causes airborne contamination, how could</p> <p>14 you have reached your conclusion that it doesn't cause</p> <p>15 infections?</p> <p>16 <b>A. Because I --</b></p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question.</p> <p>19 <b>A. I have looked at the information that I</b></p> <p>20 <b>believe is available. I don't think I'm missing any</b></p> <p>21 <b>of the information that has to do with whether the</b></p> <p>22 <b>Bair Hugger causes infection. And other than two</b></p> <p>23 <b>studies, which I believe to be inadequate, I find no</b></p> <p>24 <b>evidence that it causes infection.</b></p> <p>25 Q. You -- you're -- you're not answering my</p>
<p style="text-align: right;">Page 98</p> <p>1 question.</p> <p>2 <b>A. I think we earlier went over the fact that</b></p> <p>3 <b>I've agreed that the presence of such intermediary</b></p> <p>4 <b>mechanisms in the absence of infections poses an</b></p> <p>5 <b>interesting hypothesis, but that in the absence of</b></p> <p>6 <b>infections it is insufficient to show causation.</b></p> <p>7 Q. Well am I correct in stating that you didn't</p> <p>8 look at the issue, in connection with the conclusion</p> <p>9 you just stated, as to whether use of the Bair Hugger</p> <p>10 can create airborne contamination which can lead to</p> <p>11 infection?</p> <p>12 <b>A. I -- I think I've already answered this but</b></p> <p>13 <b>let's try it one more time. I have read a number of</b></p> <p>14 <b>papers that had to do with the question of whether the</b></p> <p>15 <b>Bair Hugger did or did not cause increase in airborne</b></p> <p>16 <b>particulates, but I have no opinion as to whether that</b></p> <p>17 <b>is the cause and whether that causes. My opinion</b></p> <p>18 <b>rests upon whether there is evidence the Bair Hugger</b></p> <p>19 <b>causes infection, and that is the basis of my opinion.</b></p> <p>20 Q. Can you answer my question? I'll read it</p> <p>21 back to you.</p> <p>22 Am I correct in stating that you didn't look</p> <p>23 at the issue, in connection with the conclusion you</p> <p>24 just stated, as to whether the use of the Bair Hugger</p> <p>25 can create airborne contamination which can lead to</p>	<p style="text-align: right;">Page 100</p> <p>1 question, so --</p> <p>2 <b>A. I -- I am really trying to answer your</b></p> <p>3 <b>question.</b></p> <p>4 Q. Okay.</p> <p>5 <b>A. You're asking the same question, I think,</b></p> <p>6 <b>repeatedly, but --</b></p> <p>7 Q. No, because you're --</p> <p>8 Well if I am, it's because you're not</p> <p>9 answering it. My ques --</p> <p>10 MR. GORDON: Well move -- move to strike</p> <p>11 counsel's commentary.</p> <p>12 Q. Did you find -- did you find it important at</p> <p>13 all, looking at this document today, to see that the</p> <p>14 manufacturer of the Bair Hugger 750 warned in an FDA</p> <p>15 document about the risk of airborne contamination</p> <p>16 through use of the Bair Hugger?</p> <p>17 <b>A. I think it's interesting.</b></p> <p>18 Q. Is this something that you wish you would</p> <p>19 have had before you rendered your opinions in this</p> <p>20 case, or are you saying it's of no import?</p> <p>21 <b>A. I'm saying that in the absence of evidence</b></p> <p>22 <b>of infections, the fact that this happens doesn't seem</b></p> <p>23 <b>to me to be central to my opinions.</b></p> <p>24 Q. Okay. Why would they be warning about</p> <p>25 airborne contamination if it wasn't increasing a risk</p>

25 (Pages 97 to 100)



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<p style="text-align: right;">Page 101</p> <p>1 of infection?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, it assumes facts not in evidence, lack of</p> <p>4 foundation.</p> <p>5 <b>A. The question is "Why would they have done</b></p> <p>6 <b>it?" I think they were required to. And I don't</b></p> <p>7 <b>think that there was evidence at that time that this</b></p> <p>8 <b>was leading to infections.</b></p> <p>9 Q. Well okay. First of all, you have no idea</p> <p>10 because you just told me you don't know what a 510(k)</p> <p>11 is, so when you state that, you have no idea whether</p> <p>12 they're required to do that or not.</p> <p>13 <b>A. Yes, but --</b></p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 <b>A. -- your question -- your question was</b></p> <p>17 <b>whether I had an opinion about why they did it. I</b></p> <p>18 <b>think that was your question.</b></p> <p>19 Q. Do you see where it says, "Prevention of</p> <p>20 airborne contamination" underneath the safety</p> <p>21 concerns, and it says, "Prevention of airborne</p> <p>22 contamination: All Bair Hugger Blankets designed for</p> <p>23 use in the operating room feature a tape barrier which</p> <p>24 prevent air from migrating toward the surgical site."</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 103</p> <p>1 whether airborne contamination could occur over the</p> <p>2 surgical site if a tape barrier weren't in place?</p> <p>3 <b>A. I did not look at that question</b></p> <p>4 <b>specifically.</b></p> <p>5 Q. Okay. And then you see it talks about</p> <p>6 "Additionally, air is filtered through a .2 micron</p> <p>7 filter." Do you see that?</p> <p>8 <b>A. I do see that.</b></p> <p>9 Q. Do you know why a manufacturer would be</p> <p>10 concerned about filtering air before sending it</p> <p>11 through the Bair Hugger?</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question.</p> <p>14 <b>A. I -- I can imagine, but it's purely</b></p> <p>15 <b>conjecture.</b></p> <p>16 Q. It wasn't something that you investigated in</p> <p>17 connection with the opinions that you've rendered;</p> <p>18 correct, sir?</p> <p>19 <b>A. Yes, that's correct.</b></p> <p>20 Q. And you didn't do any investigation into the</p> <p>21 filter efficiency of the Bair Hugger; correct?</p> <p>22 <b>A. No, I specifically did not look at the</b></p> <p>23 <b>filter efficiency of the Bair Hugger.</b></p> <p>24 <b>Would -- would you finish reading that</b></p> <p>25 <b>paragraph?</b></p>
<p style="text-align: right;">Page 102</p> <p>1 <b>A. Yes. Point to which line you have just read</b></p> <p>2 <b>to me so I'm sure that I am on track here.</b></p> <p>3 Q. Right under "Prevention of airborne</p> <p>4 contamination." Right?</p> <p>5 <b>A. Yes, I see that paragraph.</b></p> <p>6 Q. Colon, "All Bair Hugger Blankets designed</p> <p>7 for use in the operating room feature a tape barrier</p> <p>8 which prevent air from migrating toward the surgical</p> <p>9 site."</p> <p>10 <b>A. I read that, yes.</b></p> <p>11 Q. Okay. Why would the manufacturer of a Bair</p> <p>12 Hugger have a tape barrier to prevent air from</p> <p>13 migrating toward the surgical site?</p> <p>14 MR. GORDON: Objection, lack of foundation.</p> <p>15 <b>A. I -- I'm -- I'm conjecturing. You</b></p> <p>16 <b>understand I'm not an engineer, I'm not a biomedical</b></p> <p>17 <b>expert. I assume they're doing it to keep air from</b></p> <p>18 <b>leaving the blanket, but I -- that's just a</b></p> <p>19 <b>conjecture.</b></p> <p>20 Q. And that would be --</p> <p>21 And this is, of course, under the section</p> <p>22 where they're talking about concern over airborne</p> <p>23 contamination; correct?</p> <p>24 <b>A. That is the caption, yes.</b></p> <p>25 Q. Okay. So did you do any investigation into</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. Document speaks for itself.</p> <p>2 <b>A. Okay.</b></p> <p>3 Q. You haven't looked at it. I'll move on.</p> <p>4 MS. CONLIN: Can you pull out Exhibit 30,</p> <p>5 please, Mr. Stirewalt, from yesterday.</p> <p>6 (Holford Exhibit 30 handed to the witness.)</p> <p>7 MS. CONLIN: That actually may not be the</p> <p>8 right one.</p> <p>9 (Discussion off the stenographic record.)</p> <p>10 BY MS. CONLIN:</p> <p>11 Q. I've handed you, sir, what's been marked as</p> <p>12 Deposition Exhibit 30, Holford Deposition Exhibit 30.</p> <p>13 MS. CONLIN: And perhaps if you could hand</p> <p>14 him, Mr. Court Reporter, Exhibit 31 as well.</p> <p>15 (Holford Exhibit 31 handed to the witness.)</p> <p>16 Q. I've handed you, sir, what's been previously</p> <p>17 marked as Holford Deposition Exhibits 30 and 31, which</p> <p>18 are excerpts from the CDC Department of Health and</p> <p>19 Human Services, Centers for Disease Control,</p> <p>20 Healthcare Infection Control Practices Advisory</p> <p>21 Committee. Have you seen --</p> <p>22 Had you seen Exhibits 30 or 31 prior to the</p> <p>23 time you rendered your expert opinions in this case?</p> <p>24 <b>A. I don't think I've read them, no.</b></p> <p>25 Q. Okay. Did you see them yesterday after</p>

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<p style="text-align: right;">Page 105</p> <p>1 Mr. -- or after Professor Holford's deposition was</p> <p>2 taken?</p> <p>3 <b>A. We may have spoken of it. I -- I may even</b></p> <p>4 <b>have seen them, but I didn't read them.</b></p> <p>5 Q. Okay. So at the time you --</p> <p>6 And -- and you've, I think, previously</p> <p>7 testified you think the CDC is a very reputable</p> <p>8 organization; correct?</p> <p>9 <b>A. Yeah. But it's a very big organization,</b></p> <p>10 <b>which means that it does have components that make</b></p> <p>11 <b>mistakes. And I have worked for CDC and I have</b></p> <p>12 <b>respect for it.</b></p> <p>13 Q. Okay. And were you aware at the time that</p> <p>14 you rendered your expert opinions in this case that</p> <p>15 the CDC Advisory Committee on Healthcare Infection</p> <p>16 Control Practices had suggested that nothing that</p> <p>17 blows air should be in an operating room?</p> <p>18 MR. GORDON: Object to the form of the</p> <p>19 question, misstates the evidence, assumes facts not in</p> <p>20 evidence.</p> <p>21 <b>A. I -- I am aware that they made that</b></p> <p>22 <b>statement at some time in the past, yes.</b></p> <p>23 Q. Okay. Were you aware of it at the time you</p> <p>24 rendered your expert opinions in this case?</p> <p>25 <b>A. Not specifically.</b></p>	<p style="text-align: right;">Page 107</p> <p>1 and answered.</p> <p>2 <b>A. I think I answered that no, I had not looked</b></p> <p>3 <b>at this prior to rendering my report.</b></p> <p>4 Q. Do you know whether the CDC would be</p> <p>5 concerned about airborne contamination that could</p> <p>6 infect a patient on an operating table?</p> <p>7 <b>A. It would seem reasonable that they might be</b></p> <p>8 <b>concerned about that.</b></p> <p>9 Q. But that isn't something that you reviewed</p> <p>10 prior to yesterday.</p> <p>11 MR. GORDON: Objection, asked and answered.</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. Now you don't in your expert report deal at</p> <p>14 all with the reported issues of culturing of microbes</p> <p>15 within a Bair Hugger; correct?</p> <p>16 <b>A. Correct.</b></p> <p>17 Q. And I take it you don't think that the</p> <p>18 presence of microbes within a Bair Hugger can pose a</p> <p>19 risk to a patient; correct?</p> <p>20 <b>A. No, I didn't say that.</b></p> <p>21 Q. Well risk of infection to a patient.</p> <p>22 <b>A. I said that there was, to my knowledge, no</b></p> <p>23 <b>good evidence that use of the Bair Hugger caused</b></p> <p>24 <b>infections.</b></p> <p>25 Q. And my point was: In connection with</p>
<p style="text-align: right;">Page 106</p> <p>1 Q. Okay. Did you do an investigation, once you</p> <p>2 found that out, as to why the CDC was recommending</p> <p>3 that nothing that blows air should be in an operating</p> <p>4 room, if possible?</p> <p>5 MR. GORDON: Object to the form of the</p> <p>6 question, misstates the evidence, assumes facts not in</p> <p>7 evidence.</p> <p>8 <b>A. My understanding from looking at this and</b></p> <p>9 <b>discussions with Mr. Gordon last night -- or yesterday</b></p> <p>10 <b>was that there was a subsequent algorithm or -- or --</b></p> <p>11 <b>or structure that addressed that, and that the concern</b></p> <p>12 <b>the CDC had in -- or HICPAC had at that time concerned</b></p> <p>13 <b>blowers that had interfaces with -- with water</b></p> <p>14 <b>reservoirs that were wet, and I understand the concern</b></p> <p>15 <b>was probably related to a cluster of atypical</b></p> <p>16 <b>Mycobacterium infections in the cardiothoracic</b></p> <p>17 <b>surgical area.</b></p> <p>18 Q. Can you answer my question?</p> <p>19 <b>A. Well ask me your question again then.</b></p> <p>20 Q. Sure.</p> <p>21 Did you do any investigation, prior to the</p> <p>22 time you rendered your opinion in this case, as to why</p> <p>23 the CDC was recommending that nothing that blows air</p> <p>24 should be in an operating room, if possible?</p> <p>25 MR. GORDON: Same objections, also now asked</p>	<p style="text-align: right;">Page 108</p> <p>1 reaching those opinions, you had to satisfy the issues</p> <p>2 or find them not to be of interest or import that</p> <p>3 cultures had been taken in many Bair Hugger devices</p> <p>4 with infectious microbes.</p> <p>5 <b>A. I --</b></p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question.</p> <p>8 <b>A. I understand that there have been such</b></p> <p>9 <b>studies done. I have no evidence that that has led or</b></p> <p>10 <b>been associated with infections.</b></p> <p>11 Q. Were you aware that there was an</p> <p>12 Acinetobacter baumannii outbreak that was traced to</p> <p>13 the Bair Hugger as well as another surgical unit in a</p> <p>14 hospital?</p> <p>15 MR. GORDON: Object to the form.</p> <p>16 Are -- are you saying Acinetobacter?</p> <p>17 MS. CONLIN: Yeah.</p> <p>18 MR. GORDON: Object to the form of the</p> <p>19 question, assumes facts not in evidence.</p> <p>20 <b>A. I -- I don't know that I'm aware of that.</b></p> <p>21 <b>Maybe I have read it. I don't recall.</b></p> <p>22 Q. Okay. So it wasn't anything that informed</p> <p>23 your opinions.</p> <p>24 <b>A. It did not inform my opinions.</b></p> <p>25 Q. You weren't aware that there was an</p>

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<p style="text-align: right;">Page 109</p> <p>1 Acinetobacter outbreak in Kentucky and they were able</p> <p>2 to trace the organism back to the Bair Hugger as well</p> <p>3 as another piece of equipment in the OR?</p> <p>4 <b>A. I -- I would be happy to look at that if you</b></p> <p>5 <b>have information about it. I'm not aware of it off</b></p> <p>6 <b>the top of my head.</b></p> <p>7 Q. Okay. And it wasn't something that you</p> <p>8 looked at in connection with rendering your expert</p> <p>9 opinions in this case.</p> <p>10 <b>A. No, not specifically.</b></p> <p>11 Q. Okay. Do you believe or have an opinion as</p> <p>12 to whether the presence of infectious microbes being</p> <p>13 harbored in a Bair Hugger unit can create a risk of</p> <p>14 infection for a pa -- a patient?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 <b>A. It -- it seems reasonable that it could.</b></p> <p>18 Q. But you didn't look at it.</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 <b>A. I looked to see whether there was evidence</b></p> <p>22 <b>that use of the Bair Hugger had raised significantly</b></p> <p>23 <b>the risk of infection --</b></p> <p>24 Q. Right. But you --</p> <p>25 <b>A. -- in orthopedic surgeries.</b></p>	<p style="text-align: right;">Page 111</p> <p>1 You agree with me, and I think you did</p> <p>2 earlier, that association is, at the end of the day, a</p> <p>3 matter of scientific judgment; correct?</p> <p>4 <b>A. You read me a statement that said that and I</b></p> <p>5 <b>said I didn't disagree with it.</b></p> <p>6 Q. Right. You agree with it.</p> <p>7 <b>A. It requires judgment.</b></p> <p>8 Q. Right.</p> <p>9 <b>A. It's not a matter of judgment.</b></p> <p>10 Q. And in exercising that judgment, you didn't</p> <p>11 investigate all the ways in which a Bair Hugger can</p> <p>12 actually increase the risk of infection for a</p> <p>13 plaintiff -- or a patient.</p> <p>14 <b>A. I -- I really apologize. We are banging</b></p> <p>15 <b>intellectual heads together on this particular issue.</b></p> <p>16 <b>I'm telling you that I read a lot and I am</b></p> <p>17 <b>aware of the hypothetical ways in which Bair Hugger</b></p> <p>18 <b>might contribute to infections. I don't have an</b></p> <p>19 <b>opinion as to whether any of those hypothetical</b></p> <p>20 <b>mechanisms are in fact causal, and I have said that</b></p> <p>21 <b>absent evidence that it causes infection, all of those</b></p> <p>22 <b>mechanisms are simply hypothetical. So when you ask</b></p> <p>23 <b>whether I have considered them, the answer is yes.</b></p> <p>24 <b>Did it contribute to my opinion? No, absent the</b></p> <p>25 <b>evidence of infections caused by Bair Hugger.</b></p>
<p style="text-align: right;">Page 110</p> <p>1 Q. But you didn't investigate all the ways in</p> <p>2 which it could cause that increase in infections.</p> <p>3 <b>A. No, no, no. I thought about them and I read</b></p> <p>4 <b>about them, but that was not part of my opinion.</b></p> <p>5 Q. Well when you found that there wasn't</p> <p>6 sufficient evidence for an association to exist</p> <p>7 between the use of the Bair Hugger and an increased</p> <p>8 risk of infection, is it your opinion that it was just</p> <p>9 based on your review of McGovern?</p> <p>10 <b>A. Oh, no, no, it was not limited to my review</b></p> <p>11 <b>of McGovern.</b></p> <p>12 Q. Well as an epidemiology analysis, you have</p> <p>13 to look at all of the evidence that might create a</p> <p>14 risk for a patient; correct?</p> <p>15 <b>A. Yes. And we go back to an answer I gave you</b></p> <p>16 <b>earlier -- I may not be answering your question, and I</b></p> <p>17 <b>apologize in advance -- but I said that absent valid</b></p> <p>18 <b>evidence of a causal association between Bair Hugger</b></p> <p>19 <b>and SSI, it can only be said that mechanistic studies</b></p> <p>20 <b>are coherent with a hypothetical increase, and what</b></p> <p>21 <b>you're posing to me is a hypothetical increase due to</b></p> <p>22 <b>a mechanism, and I agreed with you, it is hypothetical</b></p> <p>23 <b>and hypothetically relevant.</b></p> <p>24 Q. But you didn't look at any of the documents</p> <p>25 that might -- we'll go -- strike that.</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. But still you have to look at the evidence</p> <p>2 to reach the conclusion, sir.</p> <p>3 <b>A. I -- I --</b></p> <p>4 Q. We just looked at a bunch of documents today</p> <p>5 you've never seen.</p> <p>6 <b>A. I --</b></p> <p>7 <b>The opinion I render is based on whether or</b></p> <p>8 <b>not there is evidence of infection, not whether or not</b></p> <p>9 <b>there is evidence of a hypothetical mechanism. And we</b></p> <p>10 <b>will not be able to resolve this difference. You</b></p> <p>11 <b>would like me to say -- I think you would like me to</b></p> <p>12 <b>say that the hypothetical mechanism is sufficient to</b></p> <p>13 <b>reach a causal conclusion, and it is my opinion that</b></p> <p>14 <b>it is not.</b></p> <p>15 Q. I wasn't asking you that. I'm trying to</p> <p>16 get --</p> <p>17 <b>A. In that case, I withdraw the answer.</b></p> <p>18 Q. I'm trying to get a sense of what you did in</p> <p>19 connection with reaching your conclusions as expressed</p> <p>20 in your report, and I've been probing that area, which</p> <p>21 is what I'm asking you about.</p> <p>22 MR. GORDON: And he's told you.</p> <p>23 Q. So --</p> <p>24 I don't know if you answered this or not.</p> <p>25 You don't believe there is reason to be concerned</p>

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<p style="text-align: right;">Page 113</p> <p>1 about pathogens harbored in the Bair Hugger machine 2 itself. 3 <b>A. Oh, I don't think it's a good idea to harbor 4 pathogens in the Bair Hugger machine.</b> 5 Q. Did you look at any of the documents that 6 related to -- strike that. 7 (Exhibit 10 was marked for 8 identification.) 9 BY MS. CONLIN: 10 Q. I've handed you, sir, what's been marked as 11 Deposition Exhibit No. 10, which is a series of 12 internal e-mails produced by 3M in the case. I'd like 13 to direct your attention to the second page at the 14 bottom. 15 <b>A. Bear with me. I'm just looking to see 16 things like dates and so forth. And let me just --</b> 17 Q. Dated March 3rd, 2009. 18 <b>A. Right. Oh, 2009. That's what I was looking 19 at. Yes, please go ahead.</b> 20 Q. Okay. So if you can take a look at the last 21 page, please, bottom e-mail from Judy Hodges to Rick 22 Mathieu, "Subject: Bair Hugger," reads, "Rick, 23 "We have a model 750 unit, serial number 24 19137 that has cultured positive for Acinetobacter. 25 We are looking for directions for proper cleaning/</p>	<p style="text-align: right;">Page 115</p> <p>1 of -- or worried about airborne contamination that 2 might cause an infection in a patient? 3 MR. GORDON: Lack -- 4 Objection, lack of foundation. 5 <b>A. I think they were concerned about how to 6 clean the machine and they removed a filter and threw 7 it away in the biohazards waste. I'm guessing that 8 they threw it away because they couldn't clean it, but 9 I don't know if that's true.</b> 10 Q. Can you answer my question? 11 <b>A. I have no knowledge here or no information 12 here as to whether this has to do with airborne 13 hazards.</b> 14 Q. My reading that, do you think they were 15 worried about airborne contamination that might infect 16 a patient? 17 MR. GORDON: Object to the form of the 18 question, lack of foundation. 19 <b>A. I -- I don't know. I assume that would have 20 been among the myriad thoughts that might have been, 21 but I don't know.</b> 22 Q. Okay. Did you look at any internal 23 documents about -- from 3M about machines that had -- 24 were coming out of the field that were testing 25 positive for various infectious microbes?</p>
<p style="text-align: right;">Page 114</p> <p>1 disinfecting this machine, inside and out." 2 And if we can look, then, there's a series 3 of e-mails. When you look back to the first page, Al 4 Van Duren -- in the middle of the page, Al Van Duren 5 writes to Mark Scott with a cc to Gary Hansen and Dave 6 Westlin. 7 Do you know who any of those people are, by 8 the way? 9 <b>A. No.</b> 10 Q. Okay. And it says, "Do not scrap the unit. 11 "Remove and discard the filter (in the 12 biohazardous waste)." 13 Do you see that? 14 <b>A. I do.</b> 15 Q. Why -- why do you think that representatives 16 for 3M would be concerned about changing out a filter 17 when a machine has tested positive for Acinetobacter? 18 MR. GORDON: Object to the form of the 19 question, and lack of foundation. 20 <b>A. I -- I can -- I can only conjecture. I 21 think that if there were bacteria in the machine, then 22 there might be bacteria on the filter, and it's 23 possible that the machine but not the filter can be 24 cleaned, but I don't know.</b> 25 Q. Do you think they were warned -- warned</p>	<p style="text-align: right;">Page 116</p> <p>1 <b>A. I don't think I did.</b> 2 Q. Or what 3M did in connection with those 3 reports coming in from the field? 4 MR. GORDON: Object to the form of the 5 question. 6 <b>A. No, I don't think so.</b> 7 Q. Okay. And you don't know and didn't do 8 investigation whether they were concerned about 9 airborne contamination consistent with the FDA 10 document we looked at earlier. 11 MR. GORDON: Object to the form of the 12 question. 13 <b>A. I -- I think you have shown me documents 14 that suggest that they had concerns, but I don't know.</b> 15 MS. CONLIN: Okay. Why don't we take a 16 break there. 17 THE REPORTER: Off the record, please. 18 (Recess taken.) 19 BY MS. CONLIN: 20 Q. You can direct your attention, sir, to page 21 four of your expert report, Borak Exhibit 1. In the 22 first full paragraph you say, "But as discussed below, 23 there's insufficient evidence to demonstrate that 24 forced-air warming increases the probability of deep 25 joint infection under either scenario. That was the</p>

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<p style="text-align: right;">Page 117</p> <p>1 conclusion of the recent CDC Guideline for  2 Professional -- for Prevention of Surgical Site  3 Infection." Do you see that?  4 <b>A. Yes.</b>  5 Q. And then you say, "Likewise, the nonprofit  6 ECRI recently concluded:  7 "Based on our focused systematic review of  8 the published literature, we believe that there is  9 insufficient evidence to establish that the use of  10 forced-air warming systems leads to an increase in  11 SSIs compared to other warming methods."  12 Do you see that?  13 <b>A. I do.</b>  14 Q. And that was something that you reviewed and  15 relied on in connection with your expert opinion in  16 this case.  17 <b>A. I cited it, yes.</b>  18 Q. By citing it, you relied on it; correct?  19 <b>A. That's correct.</b>  20 Q. Okay. Did you ask the attorneys for 3M, Mr.  21 Gordon or otherwise, for information that would show  22 3M's involvement in any of these publications that are  23 coming out?  24 <b>A. No.</b>  25 Q. Did you think that was anything that would</p>	<p style="text-align: right;">Page 119</p> <p>1 <b>A. It's possible.</b>  2 <b>(Borak Exhibit 11 was marked for</b>  3 <b>identification.)</b>  4 THE WITNESS: Thank you.  5 BY MS. CONLIN:  6 Q. I have handed you, sir, what's been marked  7 as Borak Deposition Exhibit 11, which is an internal  8 3M document, timeframe of February 6th and -- 5th, 6th  9 and 7th, 2011, so this would have been prior to the  10 time the ECRI publication came out that you reference  11 in your report as reference number five. And if you  12 can take a look at the top of it, it's an e-mail from  13 Gary Hansen to Dave Westlin, Teri Woodwick-Sides, Jana  14 Stender and John Rock.  15 Do you know who any of those individuals  16 are?  17 <b>A. I do not.</b>  18 Q. Okay. Do you know whether they were  19 involved in the ECRI publication that you relied on?  20 <b>A. I don't recognize the names.</b>  21 Q. Were you aware that they were involved in  22 the ECRI publication that you relied on?  23 <b>A. I am not aware.</b>  24 Q. Okay. You see it says, "I was thinking  25 about this over the weekend. Our first step with ECRI</p>
<p style="text-align: right;">Page 118</p> <p>1 be important if you're relying on certain studies?  2 <b>A. I would not have thought of that as an issue</b>  3 <b>with regards to the CDC guideline.</b>  4 <b>With regards to ECRI, I did some web</b>  5 <b>searching on it, discovered it was an organization</b>  6 <b>that was perhaps 50 or more years old, that it had a</b>  7 <b>very extensive participation. I looked at its board</b>  8 <b>and I think maybe senior staff, whatever. But it</b>  9 <b>seemed to me to be more than a public-relations</b>  10 <b>effort. I was concerned because it was not a group</b>  11 <b>that I normally deal with at great length.</b>  12 Q. Was the ECRI publication something that was  13 provided to you by the attorneys for 3M?  14 <b>A. It's likely, but I'm not -- I don't remember</b>  15 <b>specifically.</b>  16 Q. Okay. It's possible that it came from 3M in  17 the packet of materials that you reviewed?  18 <b>A. It is possible.</b>  19 Q. Okay. You don't have any independent  20 recollection of finding it on your own.  21 <b>A. I -- I don't know whether it came up as a</b>  22 <b>consequence of searching the web on forced-air warmers</b>  23 <b>and Bair Huggers. May have, but I don't remember.</b>  24 Q. Okay. But it's quite possible it came from  25 3M.</p>	<p style="text-align: right;">Page 120</p> <p>1 should be preventing them from doing their own  2 testing, but rather to rely on published data." Do  3 you see that?  4 <b>A. I see that statement.</b>  5 Q. Why do you think individuals at 3M didn't  6 want ECRI to do their own testing with respect to the  7 Bair Hugger?  8 MR. GORDON: Objection, lack of foundation.  9 <b>A. I -- I don't know.</b>  10 Q. Would that concern you as an epidemiologist  11 if the manufacturer was trying to prevent studies from  12 going on?  13 MR. GORDON: Object to the form of the  14 question.  15 <b>A. I -- I don't know whether the motivation</b>  16 <b>was -- was financial or otherwise.</b>  17 Q. Do you --  18 Are you aware that outside doctors and  19 advisors were suggesting to 3M that they do their own  20 studies on the Bair Hugger and they refused?  21 MR. GORDON: Object to the form of the  22 question, lack of foundation.  23 <b>A. I'm not aware of that.</b>  24 Q. Well when you say there's insufficient  25 evidence, did you ascertain whether the paucity of</p>

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<p style="text-align: right;">Page 121</p> <p>1 evidence as you've described is due to the fact that</p> <p>2 3M refused to do their own testing?</p> <p>3 MR. GORDON: Object to the form of the</p> <p>4 question, assumes facts not in evidence.</p> <p>5 <b>A. I have no idea.</b></p> <p>6 Q. Were you aware that representatives from 3M</p> <p>7 actually met with ECRI before that publication?</p> <p>8 <b>A. I am not aware.</b></p> <p>9 Q. Were you aware that ECRI sent that</p> <p>10 publication to 3M for comment before it was published?</p> <p>11 <b>A. I am not aware.</b></p> <p>12 Q. Would that be something that you would have</p> <p>13 wanted to know?</p> <p>14 <b>A. I would find it interesting.</b></p> <p>15 Q. Why would you find it interesting?</p> <p>16 <b>A. Because I didn't know it before and it's an</b></p> <p>17 <b>interesting facet.</b></p> <p>18 <b>I don't know whether 3M rewrote it. Is that</b></p> <p>19 <b>the implication of your question? I don't know what</b></p> <p>20 <b>happened.</b></p> <p>21 Q. But why would you find it interesting?</p> <p>22 <b>A. Because I did not know, prior to five</b></p> <p>23 <b>minutes ago, that there was any correlation between 3M</b></p> <p>24 <b>and ECRI.</b></p> <p>25 Q. Would it -- would it have been of interest</p>	<p style="text-align: right;">Page 123</p> <p>1 relied on the ECRI publication as evidence that</p> <p>2 forced-air warming doesn't increase risk of infection?</p> <p>3 <b>A. Your -- your question is whether I would</b></p> <p>4 <b>have wanted to know because I thought that 3M was</b></p> <p>5 <b>manipulating the document or might have been</b></p> <p>6 <b>manipulating the document, and I don't know whether</b></p> <p>7 <b>that's the case, and I --</b></p> <p>8 <b>Whether it would be interesting to know,</b></p> <p>9 <b>it's interesting.</b></p> <p>10 Q. I'm just asking you whether it would have</p> <p>11 been something that you would have wanted to know.</p> <p>12 <b>A. I -- I don't know. It's all in hindsight.</b></p> <p>13 Q. Did you ask 3M for any information related</p> <p>14 to this ECRI publication?</p> <p>15 <b>A. No.</b></p> <p>16 Q. Were you aware that 3M was refusing to do</p> <p>17 additional studies into the Bair Hugger?</p> <p>18 MR. GORDON: Object to the form of the</p> <p>19 question, also assumes facts not in evidence.</p> <p>20 <b>A. Would you repeat your question?</b></p> <p>21 Q. Sure. Were you aware, prior to the time you</p> <p>22 issued your opinions in this case, that 3M was</p> <p>23 refusing to do any additional studies into the Bair</p> <p>24 Hugger?</p> <p>25 MR. GORDON: Same objection.</p>
<p style="text-align: right;">Page 122</p> <p>1 for you to know that 3M representatives met with ECRI</p> <p>2 officials for an in-person meeting on March 9th of</p> <p>3 2011 in Philadelphia?</p> <p>4 <b>A. I -- I don't know enough to tell you whether</b></p> <p>5 <b>it's anything of interest.</b></p> <p>6 Q. Were you aware that ECRI assured 3M that it</p> <p>7 would be a confidential discussion?</p> <p>8 <b>A. I have no knowledge of any of this.</b></p> <p>9 Q. Would that be something you would have</p> <p>10 wanted to know when you relied on the ECRI publication</p> <p>11 as evidence that forced-air warming doesn't increase</p> <p>12 risk of infection?</p> <p>13 <b>A. I read the ECRI document and I looked at the</b></p> <p>14 <b>ECRI website to understand who ECRI was. That was all</b></p> <p>15 <b>that I knew.</b></p> <p>16 Q. Can you answer my question.</p> <p>17 <b>A. You're asking me whether my opinion of their</b></p> <p>18 <b>document would have been changed by the fact that</b></p> <p>19 <b>they --</b></p> <p>20 Q. No.</p> <p>21 <b>A. -- met in Philadelphia confidentially.</b></p> <p>22 Q. That's not what I asked. It was: Would the</p> <p>23 fact that 3M officials met with ECRI in confidential</p> <p>24 discussions prior to the publication have been</p> <p>25 something that you would have wanted to know when you</p>	<p style="text-align: right;">Page 124</p> <p>1 <b>A. I -- I don't know whether that was true and</b></p> <p>2 <b>I didn't know it.</b></p> <p>3 <b>(Exhibit 12 was marked for</b></p> <p>4 <b>identification.)</b></p> <p>5 THE WITNESS: Thank you.</p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you, sir, what's been marked as</p> <p>8 Deposition Exhibit 12, which is a series of e-mails</p> <p>9 between Gary Hansen and Dan Sessler.</p> <p>10 Do you know who Mr. Sess -- Dr. Sessler is?</p> <p>11 (Glass of liquid spills on table.)</p> <p>12 MS. CONLIN: Let's go off the record.</p> <p>13 THE REPORTER: Off the record, please.</p> <p>14 (Recess taken.)</p> <p>15 THE REPORTER: There's a pending question.</p> <p>16 Q. I've handed you, sir, what's been marked as</p> <p>17 Deposition Exhibit 12, which is a series of e-mails</p> <p>18 between Gary Hansen and -- and Dr. Daniel Sessler.</p> <p>19 You know who Dr. Sessler is; correct?</p> <p>20 <b>A. I -- I know the name, yes.</b></p> <p>21 Q. And you in fact relied on some of his</p> <p>22 publications in connection with your opinions in this</p> <p>23 case; correct?</p> <p>24 <b>A. Yes, I've cited his work.</b></p> <p>25 Q. For example, in your reference list number</p>

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<p style="text-align: right;">Page 125</p> <p>1 three, the Kurz and Sessler, that was one of the</p> <p>2 references that you relied on; correct?</p> <p>3 <b>A. That we discussed earlier.</b></p> <p>4 Q. Yes.</p> <p>5 And were you aware that at the time you</p> <p>6 issued your opinion in this case that Dr. Sessler was</p> <p>7 an outside science advisor/medical doctor to 3M?</p> <p>8 <b>A. I was unaware.</b></p> <p>9 Q. So you're hearing that today for the first</p> <p>10 time?</p> <p>11 <b>A. I think so.</b></p> <p>12 Q. Okay. And if we take a look at Borak</p> <p>13 Exhibit 12, at the bottom it's an e-mail from Dr.</p> <p>14 Sessler to Gary Hansen at 3M.</p> <p>15 "Hi Gary,</p> <p>16 "We were lucky that this was published at</p> <p>17 almost the same time as Scott's paper. We may not</p> <p>18 have -- We may not have warning of his next effort</p> <p>19 though. There is a real possibility that he will do</p> <p>20 some sort of bacterial sampling study (the idea is</p> <p>21 obvious) and we'll first know of it in the published</p> <p>22 paper. If that happens, whatever Scott reports will</p> <p>23 be un-opposed for one to two years while we do a</p> <p>24 catch-up study, analysis, and get through the</p> <p>25 publication process. Waiting much longer seems like a</p>	<p style="text-align: right;">Page 127</p> <p>1 of time -- and now more to come. Furthermore, this</p> <p>2 may damage my reputation; just the fact that a</p> <p>3 complaint was filed already has to some extent."</p> <p>4 Do you see that?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. Okay. And the next paragraph, it says,</p> <p>7 "This was completely preventable. As I've been saying</p> <p>8 for a year, only a bacterial sampling study will</p> <p>9 adequately deal with this issue."</p> <p>10 Do you see that?</p> <p>11 <b>A. I see that.</b></p> <p>12 Q. Okay. So you have now seen two separate</p> <p>13 e-mails, separate in time, where Dr. Sessler is urging</p> <p>14 3M to do a study; correct?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 <b>A. I -- I'm -- I'm assuming that's what he</b></p> <p>18 <b>spoke of in the ear -- previous exhibit and his</b></p> <p>19 <b>concern is reiterated here, but I don't know that to</b></p> <p>20 <b>be certain.</b></p> <p>21 Q. If it is, you would agree with me that</p> <p>22 there's at least evidence that over a period of time</p> <p>23 Dr. Sessler was urging 3M to do a study.</p> <p>24 <b>A. Yes. There was apparently evidence that for</b></p> <p>25 <b>appar -- that at least twice over a period of</b></p>
<p style="text-align: right;">Page 126</p> <p>1 dangerous strategy."</p> <p>2 Do you see that?</p> <p>3 <b>A. Yes, that's what you read.</b></p> <p>4 Q. Were you aware that Dan Sessler was urging</p> <p>5 3M for years to do their own bacterial studies?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question.</p> <p>8 <b>A. I -- I -- I don't know that, and that's not</b></p> <p>9 <b>put forth here.</b></p> <p>10 Q. Were you aware that -- were you aware that</p> <p>11 Dr. Sessler was urging 3M to do their own bacterial</p> <p>12 studies?</p> <p>13 <b>A. I was not aware.</b></p> <p>14 <b>(Exhibit 13 was marked for</b></p> <p>15 <b>identification.)</b></p> <p>16 BY MS. CONLIN:</p> <p>17 Q. I've handed you, sir, what's been marked as</p> <p>18 Borak Deposition Exhibit 13, which is an e-mail from</p> <p>19 Dan Sessler dated -- looks like approximately a year</p> <p>20 after the e-mail we were just looking at, "Re:</p> <p>21 URGENT!!!!" Do you see that?</p> <p>22 <b>A. I see the top, yes.</b></p> <p>23 Q. Okay. And it says, "Gary,</p> <p>24 "I'm pretty unhappy. I took this project on</p> <p>25 as a favor and it has ended up costing a huge amount</p>	<p style="text-align: right;">Page 128</p> <p>1 <b>something like that, seven months, eight months, that</b></p> <p>2 <b>he had been urging that.</b></p> <p>3 Q. Okay.</p> <p>4 (Exhibit 14 was marked for</p> <p>5 identification.)</p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you what's been marked as Borak</p> <p>8 Deposition Exhibit 14. I'm just going to refer you to</p> <p>9 the top part of this e-mail chain from Mark Morton to</p> <p>10 Scott Waite, cc to Michelle Hulse Stevens, Mark Scott</p> <p>11 and Soria Immaculada, and it says --</p> <p>12 And if I could direct your attention in the</p> <p>13 first paragraph where it says "Hi Scott."</p> <p>14 <b>A. I see that.</b></p> <p>15 Q. Do you see that? Okay. And it said there</p> <p>16 was an inquiry by Dr. Stefan, to which Mr. Morken is</p> <p>17 responding: "Also would really need to understand</p> <p>18 what type of study is being proposed. Given the</p> <p>19 ongoing legal situation, decisions were previously</p> <p>20 made (at a high level) not to pursue clinical research</p> <p>21 on this topic."</p> <p>22 Do you see that?</p> <p>23 <b>A. Bear with me, I --</b></p> <p>24 <b>Yes.</b></p> <p>25 Q. Okay. And the subject is "RE: Message to</p>

32 (Pages 125 to 128)

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<p style="text-align: right;">Page 129</p> <p>1 address safety and efficacy of forced air warming."  2 Do you see that?  3 <b>A. Yes.</b>  4 Q. Were you aware that decisions were made at a  5 high level at 3M not to do any clinical research into  6 the safety and efficacy of their Bair Huggers?  7 MR. GORDON: Object to the form of the  8 question, mischaracterizes the evidence, --  9 <b>A. I had no --</b>  10 MR. GORDON: -- assumes facts not in  11 evidence.  12 <b>A. I had no prior knowledge of that.</b>  13 Q. Okay. Was that something that you would  14 have thought was important for you to know in  15 connection with your opinion that there's a lack of  16 evidence showing that the Bair Hugger increases  17 infection risk?  18 MR. GORDON: Same objection.  19 <b>A. It -- it would be interesting to know. But</b>  20 <b>as I told you, my opinion rested upon the association</b>  21 <b>between the use of Bair Hugger and infections.</b>  22 Q. Right. And you -- and you understand, based  23 on looking at that, that 3M refused to do further  24 research into that topic; correct?  25 <b>A. I don't know that that was the topic about</b></p>	<p style="text-align: right;">Page 131</p> <p>1 do you believe that The Reference Guide on  2 Epidemiology by Green, Friedman and Gordis is an  3 authoritative work?  4 <b>A. I think it's very good work. I reference</b>  5 <b>it.</b>  6 Q. Okay. And you've never taken any issue with  7 anything that they've said in connection with that  8 reference manual.  9 <b>A. Not that I remember.</b>  10 Q. Did you do --  11 If we can take a look at page four, footnote  12 one.  13 MR. GORDON: Of his report?  14 MS. CONLIN: Borak Exhibit 1, his expert  15 report.  16 <b>A. Yes.</b>  17 Q. Did you do any investigation into the  18 efficacy of the Bair Hugger vis-a-vis another type of  19 warming device?  20 MR. GORDON: Object to the form of the  21 question.  22 <b>A. I -- I thought that I had read the published</b>  23 <b>literature that might have addressed that. I'm not</b>  24 <b>sure that there was anything other, at the time that I</b>  25 <b>did my report, than McGovern, but there may have been</b></p>
<p style="text-align: right;">Page 130</p> <p>1 <b>which they refused to do research. There is talk here</b>  2 <b>that says that they decided not to pursue clinical</b>  3 <b>research work on this topic; I am not sure what the</b>  4 <b>topic was.</b>  5 Q. Well read the subject line.  6 <b>A. "Message to address safety and efficacy of</b>  7 <b>forced air warming." I'm sure they were not doing</b>  8 <b>research on the message. And "safety and efficacy" is</b>  9 <b>a very broad and vague area. I don't know what the</b>  10 <b>clinical research was proposed.</b>  11 Q. Well are you aware of any other safety and  12 efficacy issues on the Bair Hugger other than the risk  13 of infection through airborne contamination?  14 MR. GORDON: Object to the form of the  15 question.  16 <b>A. I think that safety and efficacy are two</b>  17 <b>separate issues and I don't know which aspects of</b>  18 <b>either was their concern here. You're asking me to</b>  19 <b>respond to an e-mail which I find unclear.</b>  20 Q. Okay. With respect to the safety of the  21 Bair Hugger, are you aware of any concerns other than  22 the risk of airborne contamination at the time you  23 rendered your opinion in this case?  24 <b>A. I am not specifically aware of any, no.</b>  25 Q. Okay. I may have asked you this before, but</p>	<p style="text-align: right;">Page 132</p> <p>1 <b>others. I don't remember it.</b>  2 Q. My question is a little different. Did  3 you --  4 Are you rendering an opinion on the efficacy  5 of the Bair Hugger as it relates to maintaining  6 normothermia vis-a-vis any other warming device?  7 <b>A. Ahh. I'm sorry. I misunderstood your</b>  8 <b>question.</b>  9 <b>I was not going to render such an opinion.</b>  10 <b>My understanding is that the --</b>  11 Q. I just want to know if.  12 <b>A. Okay.</b>  13 Q. If you're not rendering an opinion on it,  14 then that's all I need to know and I'll move on.  15 <b>A. Perfect. Move on.</b>  16 Q. And you didn't do any investigation into  17 that; correct?  18 <b>A. I did not do any investigation into that.</b>  19 Q. I'd like to direct your attention to page  20 six, and I'd like to get an understanding --  21 Well in paragraph 18 under "Confounding" you  22 say, "Confounding is said to occur when the  23 association between exposure and effect is distorted  24 by some third variable." Okay?  25 Does a confounder have to have association</p>

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<p style="text-align: right;">Page 133</p> <p>1 with the effect in order to be a confounder?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 <b>A. I think that some people have written about</b></p> <p>5 <b>the ability of things to influence the relationship</b></p> <p>6 <b>and to act as an intermediary, but generally I think</b></p> <p>7 <b>that a confounder should be associated with both the</b></p> <p>8 <b>exposure and the outcome.</b></p> <p>9 Q. Okay. There has to be an association.</p> <p>10 <b>A. I believe so.</b></p> <p>11 Q. Okay. And is that the definition that you</p> <p>12 used in connection with your opinions on the</p> <p>13 confounding elements that you set forth in your</p> <p>14 report?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. All right. I'd like to direct your</p> <p>17 attention to page 14 of your report and first focus</p> <p>18 on, starting on paragraph 41, antithrombotic</p> <p>19 prophylaxis. Okay?</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. Okay. You found that the change in</p> <p>22 antithrombotic -- thrombotic -- botic prophylaxis, the</p> <p>23 change from trinzaparin to Xarelto, was a confounder;</p> <p>24 is that right?</p> <p>25 <b>A. I think that the use of different</b></p>	<p style="text-align: right;">Page 135</p> <p>1 deep vein thrombosis is associated with the risk of</p> <p>2 infection, in the Bair Hugger it's not; correct?</p> <p>3 <b>A. I'm sorry, say that again.</b></p> <p>4 Q. Well you said there's an association between</p> <p>5 antithrombotic drugs and your risk of infection;</p> <p>6 correct?</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question.</p> <p>9 <b>A. Yes, ultimately.</b></p> <p>10 Q. Okay. So there's an association between</p> <p>11 that and infection, but not the Bair Hugger and</p> <p>12 infection; correct?</p> <p>13 <b>A. The issue concerns the use of different</b></p> <p>14 <b>medications differentially with different warming</b></p> <p>15 <b>devices, which led to a mixing and confusion of</b></p> <p>16 <b>effects.</b></p> <p>17 Q. Can you answer my question?</p> <p>18 <b>A. But your question can't be answered "yes" or</b></p> <p>19 <b>"no." I don't think it can be.</b></p> <p>20 Q. Well you said there's an infec -- there's an</p> <p>21 association between antithrombotic prophylaxis drugs</p> <p>22 and risk of infection; correct?</p> <p>23 <b>A. Yes.</b></p> <p>24 Q. Okay. But there isn't an association</p> <p>25 between the use of the Bair Hugger and risk of</p>
<p style="text-align: right;">Page 134</p> <p>1 <b>antithrombotic medications confounded the association</b></p> <p>2 <b>between warming devices and surgical infections, yes.</b></p> <p>3 Q. Well you -- you previously testified that</p> <p>4 there has to be an association between the potential</p> <p>5 confounder and the outcome for it to be a confounder;</p> <p>6 correct?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Okay. So there is an association between</p> <p>9 the antithrombotic prophylaxis and the risk of</p> <p>10 infection?</p> <p>11 <b>A. I believe so.</b></p> <p>12 Q. Okay. And what do you understand an</p> <p>13 antithrombotic drug to do?</p> <p>14 <b>A. Its purpose is to prevent the formation of</b></p> <p>15 <b>deep vein thromboses and pulmonary emboli. It</b></p> <p>16 <b>essentially down-regulates the clotting system.</b></p> <p>17 Q. Okay. And that is there's an association</p> <p>18 between which drug you use and your chance of</p> <p>19 infection; correct?</p> <p>20 MR. GORDON: Object to the form of the</p> <p>21 question.</p> <p>22 <b>A. I believe that there is, probably because of</b></p> <p>23 <b>the ability of the two drugs to differentially</b></p> <p>24 <b>influence bleeding in the wound site.</b></p> <p>25 Q. Okay. So what medication you get to avoid</p>	<p style="text-align: right;">Page 136</p> <p>1 infection; correct?</p> <p>2 <b>A. I said I wasn't aware of evidence that there</b></p> <p>3 <b>was an association. That was way back earlier in the</b></p> <p>4 <b>deposition.</b></p> <p>5 Q. Well I understand, --</p> <p>6 <b>A. Okay.</b></p> <p>7 Q. -- but I'm just trying to get --</p> <p>8 So the -- the use of a drug --</p> <p>9 It thins your blood; right?</p> <p>10 <b>A. Correct.</b></p> <p>11 Q. -- can be associated with the risk of</p> <p>12 infection; correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. But the Bair Hugger is not, based on your</p> <p>15 opinion.</p> <p>16 <b>A. The evidence on the antithrom --</b></p> <p>17 <b>I find that you are mingling things and I</b></p> <p>18 <b>can't respond "yes" or "no." They are separate. I</b></p> <p>19 <b>find that there is insufficient evidence that the Bair</b></p> <p>20 <b>Hugger causes infection. I think that there is</b></p> <p>21 <b>evidence that the antithrombotic agents can contribute</b></p> <p>22 <b>and increase the risk of infection, and I think that</b></p> <p>23 <b>the use of the different antithrombotic agents in the</b></p> <p>24 <b>context of the McGovern study, in which the two</b></p> <p>25 <b>warming devices were used differentially with regards</b></p>

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<p style="text-align: right;">Page 137</p> <p>1 to the thrombotic agents -- antithrombotic agents, may</p> <p>2 have resulted in the appearance of an association</p> <p>3 between the warming unit and the risk.</p> <p>4 Q. Well you find that the switch in</p> <p>5 antithrombotic agents was a confounder; correct?</p> <p>6 A. It's not so much the -- the switch, but yes,</p> <p>7 the thrombotic agents were a confounder.</p> <p>8 Q. Yes.</p> <p>9 A. A different confounder.</p> <p>10 Q. And to be a confounder, there has to be an</p> <p>11 association.</p> <p>12 A. Yes.</p> <p>13 Q. Okay. So how is it that an antithrombotic</p> <p>14 drug can increase your risk of infection?</p> <p>15 A. By increasing the risk of bleeding, bleeding</p> <p>16 being -- the blood being a fantastic culture medium</p> <p>17 for bacteria and encourages infection.</p> <p>18 Q. Okay. Did you -- do you have any</p> <p>19 understanding --</p> <p>20 Did you investigate how vascular the joint</p> <p>21 area is in which a knee or hip implant would be going</p> <p>22 in?</p> <p>23 A. I -- I don't think it's necessarily in the</p> <p>24 joint itself. But I have seen evidence that the use</p> <p>25 of different medications increases a lot the -- or it</p>	<p style="text-align: right;">Page 139</p> <p>1 A. I guess I read them and made judgments based</p> <p>2 upon what I read.</p> <p>3 Q. Does the use of a thromboprophylactic</p> <p>4 increase bacteria in a prosthetic joint?</p> <p>5 A. I've --</p> <p>6 There's evidence that use of different</p> <p>7 antithrombotics can increase the risk of infections in</p> <p>8 the joint.</p> <p>9 Q. My question was a little different.</p> <p>10 A. I understand. I -- I told you earlier I</p> <p>11 didn't know that much about the blood flow to the</p> <p>12 joint, but I know there is evidence to sugg --</p> <p>13 indicate that there is increased risk of joint</p> <p>14 infections postoperatively affected by the choice of</p> <p>15 antithrombotic.</p> <p>16 Q. Can you answer --</p> <p>17 A. That's all that I can opine to.</p> <p>18 Q. Do you know whether the use of an</p> <p>19 antithrombotic prophylaxis increases the number of</p> <p>20 bacteria on a prosthetic joint?</p> <p>21 A. I don't know that.</p> <p>22 Q. Okay. That wasn't something that you took</p> <p>23 into account?</p> <p>24 A. I wouldn't have taken that into account.</p> <p>25 Q. Okay. Do you know whether the use of an</p>
<p style="text-align: right;">Page 138</p> <p>1 alters a lot the risk of bleeding into the surgery.</p> <p>2 Q. Okay. And I'm talking about the actual</p> <p>3 joint.</p> <p>4 A. I haven't looked into that.</p> <p>5 Q. Okay. You're aware that the authors of the</p> <p>6 McGovern study looked at this issue and concluded that</p> <p>7 they didn't view the change in antithrombotic</p> <p>8 prophylaxis to be a confounder; correct?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question.</p> <p>11 A. I -- I believe they testified that they</p> <p>12 thought it was a potential confounder.</p> <p>13 Q. Do you recall?</p> <p>14 A. I can read.</p> <p>15 Q. I'll pull it out for you.</p> <p>16 A. Both read, -a-d, and -e-d.</p> <p>17 Q. Well when did you decide that you were going</p> <p>18 to rely on what the McGovern authors said and how did</p> <p>19 you go about sorting what you were going to rely upon</p> <p>20 out of their depositions and what you were going to</p> <p>21 set aside as not believing?</p> <p>22 MR. GORDON: I object to the form of the</p> <p>23 question, assumes facts not in evidence, compound.</p> <p>24 A. How did I decide?</p> <p>25 Q. Uh-huh.</p>	<p style="text-align: right;">Page 140</p> <p>1 antithrombotic prophylaxis increases the number of</p> <p>2 particles over a surgical site during operation?</p> <p>3 A. I have no knowledge about that.</p> <p>4 Q. Do you know when an antithrombotic</p> <p>5 prophylaxis drug is administered in connection with an</p> <p>6 orthopedic implant?</p> <p>7 A. My understanding is it's first administered</p> <p>8 postoperatively.</p> <p>9 Q. Okay. So it's your opinion that there is an</p> <p>10 a priori relationship between use of a particular</p> <p>11 antithrombotic prophylaxis and risk of infection.</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question.</p> <p>14 A. I'm not sure what you mean by "an a priori."</p> <p>15 Q. Do you know what that means, what that term</p> <p>16 means in connection with an epidemiologic undertaking?</p> <p>17 A. I -- I have seen it used. I'm interested to</p> <p>18 know how you're using it in your question.</p> <p>19 Q. Well how -- how would --</p> <p>20 How do you define it?</p> <p>21 A. As a given.</p> <p>22 Q. Okay. In connection with your opinions</p> <p>23 here, when, for example in paragraph 44 --</p> <p>24 Well let me -- let me back -- let me ask it</p> <p>25 more generally.</p>

35 (Pages 137 to 140)

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<p style="text-align: right;">Page 141</p> <p>1 In connection with your conclusions that</p> <p>2 there is an association between what antithrombotic</p> <p>3 prophylaxis drug is used and your risk of infection,</p> <p>4 were you specifically focused on deep joint infection</p> <p>5 or SSIs in general?</p> <p>6 <b>A. I was specifically focused on the McGovern</b></p> <p>7 <b>and the Jensen re -- and -- reports, which I</b></p> <p>8 <b>understood to be deep joint infections.</b></p> <p>9 Q. Okay. Were you the one that suggested that</p> <p>10 Dr. Holford should reanalyze the McGovern data set</p> <p>11 using the Jensen report?</p> <p>12 <b>A. I thought it was very clever but -- and I'd</b></p> <p>13 <b>love to take credit for it, but I don't think I was.</b></p> <p>14 Q. Okay. And you didn't -- you didn't look at</p> <p>15 those numbers and see whether they were accurate and</p> <p>16 you didn't express an opinion on whether that's</p> <p>17 something that's appropriate to do or not; correct?</p> <p>18 MR. GORDON: Object to the form of the</p> <p>19 question.</p> <p>20 <b>A. I -- I think when I first read it --</b></p> <p>21 <b>You're asking me whether I suggested it.</b></p> <p>22 <b>I'm not sure that I suggested it. I know that I</b></p> <p>23 <b>remarked to myself and to no one else that the Jensen</b></p> <p>24 <b>report had a shorter followup and that the</b></p> <p>25 <b>postoperative joint infections could be delayed and</b></p>	<p style="text-align: right;">Page 143</p> <p>1 based on the results of that study, that, quote, "We</p> <p>2 can now exclude Xarelto as a confounding factor for</p> <p>3 infection rate." You're aware of that; correct?</p> <p>4 <b>A. I'm sorry, I don't remember the statement.</b></p> <p>5 Q. Okay. Was that something that would be</p> <p>6 important to you, that the author of the McGovern</p> <p>7 study did further work into the -- the use of Xarelto</p> <p>8 as an antithrombotic prophylaxis and found that -- he</p> <p>9 said that it could be excluded as a confounding factor</p> <p>10 for infection rates?</p> <p>11 <b>A. I -- I would certainly want to see it before</b></p> <p>12 <b>I rendered any opinion about it.</b></p> <p>13 Q. Are you aware that Professor Nachtsheim</p> <p>14 said the same thing?</p> <p>15 <b>A. I don't remember that particularly.</b></p> <p>16 Q. And you didn't even cite that article in</p> <p>17 your report; did you, sir?</p> <p>18 <b>A. I don't think I did, no.</b></p> <p>19 Q. Okay. So how is it that --</p> <p>20 MR. GORDON: What -- what article are you</p> <p>21 referring to?</p> <p>22 MS. CONLIN: The Reed article on Xarelto.</p> <p>23 MR. GORDON: Is he the first -- first --</p> <p>24 Q. What do you -- what do --</p> <p>25 MR. GORDON: Is he the first author?</p>
<p style="text-align: right;">Page 142</p> <p>1 <b>therefore the Jensen report might have undercounted</b></p> <p>2 <b>infections. I did not look to see the numbers of</b></p> <p>3 <b>cases which suggest that the Jensen report included</b></p> <p>4 <b>other kinds of cases other than those included in</b></p> <p>5 <b>McGovern.</b></p> <p>6 Q. You didn't express an opinion on whether</p> <p>7 what Professor Holford did in connection with his</p> <p>8 remix or reanalysis of the McGovern data set taking</p> <p>9 into account Jensen was appropriate; correct?</p> <p>10 <b>A. Did I express an opinion?</b></p> <p>11 Q. Yes.</p> <p>12 <b>A. In my writing I think I -- I accepted Dr.</b></p> <p>13 <b>Holford's reanalysis.</b></p> <p>14 <b>(Discussion off the stenographic record.)</b></p> <p>15 Q. Okay. Now you un --</p> <p>16 You understand that after McGovern, Dr. Reed</p> <p>17 published another study analyzing wound complications</p> <p>18 following the use of Xarelto.</p> <p>19 <b>A. I -- I -- I'm not surprised when you say it,</b></p> <p>20 <b>but I can't think of it right off the top. Can you</b></p> <p>21 <b>give me a title?</b></p> <p>22 Q. Not right now, but I -- I'll pull it out for</p> <p>23 you in a second.</p> <p>24 <b>A. Okay.</b></p> <p>25 Q. You're aware that Dr. Reed testified that,</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. What do you --</p> <p>2 Explain to me the mechanism by which the use</p> <p>3 of Xarelto increases your infection risk over</p> <p>4 trinzaparin.</p> <p>5 <b>A. My understanding is it increases bleeding</b></p> <p>6 <b>into the wound, and that the blood in the wound is a</b></p> <p>7 <b>great culture medium and accelerates and enhances</b></p> <p>8 <b>infection.</b></p> <p>9 Q. Well both are antithrombotic; correct?</p> <p>10 <b>A. Correct, but by different mechanisms.</b></p> <p>11 Q. So --</p> <p>12 <b>A. And my understanding is that there is a</b></p> <p>13 <b>differential in the rate of postoperative bleeds when</b></p> <p>14 <b>rivaroxaban was used.</b></p> <p>15 Q. Well rivaroxaban is Xarelto; correct?</p> <p>16 <b>A. Correct.</b></p> <p>17 Q. Okay. And what's that based on?</p> <p>18 <b>A. The literature that I have reviewed. It's</b></p> <p>19 <b>clearly in the Jensen paper, it's probably in others,</b></p> <p>20 <b>but I -- I can't make this a memory test and I</b></p> <p>21 <b>apologize. But Jensen certainly indicates increased</b></p> <p>22 <b>risks with rivaroxaban.</b></p> <p>23 Q. We'll get to Jensen in a second. I'm just</p> <p>24 asking you if you understand the mechanism by which</p> <p>25 you think that use of trinzaparin creates a lower risk</p>

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<p style="text-align: right;">Page 145</p> <p>1 for infection than Xarelto.</p> <p>2 <b>A. I understand that tinza -- tinzap --</b></p> <p>3 <b>trinzaparin -- I don't know how to say it, but I</b></p> <p>4 <b>believe it's trinzaparin -- I believe that it is</b></p> <p>5 <b>associated with less wound bleeding postoperatively.</b></p> <p>6 Q. We'll just go there. Hold on.</p> <p>7 (Exhibit 15 was marked for</p> <p>8 identification.)</p> <p>9 THE WITNESS: Thank you.</p> <p>10 BY MS. CONLIN:</p> <p>11 Q. I've handed you what's been marked as Borak</p> <p>12 Deposition Exhibit 15, which is an article entitled</p> <p>13 "Return to the surgery following total hip and knee</p> <p>14 replacement, before and after the introduction of</p> <p>15 rivaroxaban." Do you see that?</p> <p>16 <b>A. I do.</b></p> <p>17 Q. And the rivaroxaban is Xarelto; correct?</p> <p>18 <b>A. I believe so.</b></p> <p>19 Q. Okay. And is this the study that you're</p> <p>20 referencing?</p> <p>21 <b>A. I believe it is. I've looked at it in a</b></p> <p>22 <b>different format, so it's --</b></p> <p>23 <b>It was a pdf, printed in a different format,</b></p> <p>24 <b>but I think it's correct.</b></p> <p>25 Q. Okay. Do you see the third author listed</p>	<p style="text-align: right;">Page 147</p> <p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 Q. You haven't done an investigation beyond</p> <p>4 what you -- what you've read; correct?</p> <p>5 <b>A. I have not directly studied the use of</b></p> <p>6 <b>Xarox -- Xarelto.</b></p> <p>7 Q. Okay. What investigation did you do other</p> <p>8 than read the couple of articles that are cited in</p> <p>9 your report?</p> <p>10 <b>A. Well I've read a lot of articles. Only</b></p> <p>11 <b>those cited are the ones I specifically was relying</b></p> <p>12 <b>upon. I don't want to diminish the effort that was</b></p> <p>13 <b>put into it, but I read the literature.</b></p> <p>14 Q. Okay. With respect to this issue of Xarelto</p> <p>15 being a potential confounder --</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. -- for the risk of infection in knee and hip</p> <p>18 surgeries, what other articles do you have in mind</p> <p>19 other than those that you cited in your report?</p> <p>20 <b>A. I think at the moment those are the ones</b></p> <p>21 <b>specifically that I would name.</b></p> <p>22 Q. And to the extent that Dr. Reed, an author</p> <p>23 of this study, said that this study proves that</p> <p>24 Xarelto is not a confounder in knee and hip surgery,</p> <p>25 you would disagree with him.</p>
<p style="text-align: right;">Page 146</p> <p>1 there?</p> <p>2 <b>A. Is it Partington?</b></p> <p>3 Q. No, that would be the -- well do you see --</p> <p>4 I guess it would be the fourth then. Do you</p> <p>5 see the fourth author there?</p> <p>6 <b>A. Dr. Reed.</b></p> <p>7 Q. Okay. Are you aware that Dr. Reed testified</p> <p>8 that this study showed no --</p> <p>9 Well strike it. Let me ask it a different</p> <p>10 way.</p> <p>11 Are you aware that Dr. Reed testified that</p> <p>12 this study eliminates Xarelto as a confounder for</p> <p>13 infection risks in knee and hip surgeries?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 <b>A. I'm --</b></p> <p>17 <b>I don't remember that he said that, but I</b></p> <p>18 <b>think it's wrong.</b></p> <p>19 Q. Okay. So you don't remember reading it, but</p> <p>20 if he said it, he's wrong.</p> <p>21 <b>A. I believe it does not eliminate it. Yes,</b></p> <p>22 <b>that's correct.</b></p> <p>23 Q. Okay. And he's somebody who has</p> <p>24 investigated this issue. You're somebody who has read</p> <p>25 some articles. Correct?</p>	<p style="text-align: right;">Page 148</p> <p>1 <b>A. Did he say that here?</b></p> <p>2 Q. He said it in his deposition. I'm</p> <p>3 representing that to you.</p> <p>4 <b>A. I -- I don't think that this study</b></p> <p>5 <b>eliminates rivaroxaban as a confounder in the McGowan</b></p> <p>6 <b>study.</b></p> <p>7 Q. Okay. Based on what is my question.</p> <p>8 <b>A. Based on the fact that there was a</b></p> <p>9 <b>significant increase -- there was a large increase, I</b></p> <p>10 <b>think 2.5-to-one increase in infection rates, and I</b></p> <p>11 <b>think this study under-ascertained cases because it</b></p> <p>12 <b>only had a 30-day followup.</b></p> <p>13 Q. Well so you relied on it but you didn't rely</p> <p>14 on it?</p> <p>15 <b>A. No, no, no, no, no. I didn't rely upon it.</b></p> <p>16 <b>I said I think it did not prove that it was not a</b></p> <p>17 <b>confounder. Moreover, a confounder -- whether</b></p> <p>18 <b>something is or is not a confounder is not dependent</b></p> <p>19 <b>on whether it is, on a univariate level, statistically</b></p> <p>20 <b>significantly associated with the outcome or whether</b></p> <p>21 <b>it significantly influences the relationship that it</b></p> <p>22 <b>confounds.</b></p> <p>23 Q. It has to have an association.</p> <p>24 <b>A. That's a start but not a finish.</b></p> <p>25 MS. CONLIN: Okay. So why don't you pull</p>

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<p style="text-align: right;">Page 149</p> <p>1 out, Mr. Stirewalt, what was marked yesterday as</p> <p>2 Exhibit 19, because I think that is probably the pdf</p> <p>3 that he's used to seeing in connection with this</p> <p>4 study.</p> <p>5 <b>A. Maybe that one.</b></p> <p>6 <b>(Holford Exhibit 19 handed to the witness.)</b></p> <p>7 Q. I've handed you what's previously been</p> <p>8 marked as Holford Exhibit 19, which is, I believe, the</p> <p>9 same study in a different format. Is this the format</p> <p>10 that you're used to seeing this study?</p> <p>11 <b>A. Yes, that's correct.</b></p> <p>12 Q. Okay. And did you understand this study to</p> <p>13 be breaking down wound complications such as surgical</p> <p>14 wound infections versus deep joint infections?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 <b>A. You're asking me whether it specifically</b></p> <p>18 <b>differentiated different kinds of wound infections?</b></p> <p>19 Q. Deep joint versus a superficial wound</p> <p>20 infection or the like. Did you have that in mind when</p> <p>21 you reviewed this?</p> <p>22 <b>A. I don't recall having that particular</b></p> <p>23 <b>question in mind, --</b></p> <p>24 Q. Okay.</p> <p>25 <b>A. -- but I will -- would again if you'd like</b></p>	<p style="text-align: right;">Page 151</p> <p>1 that?</p> <p>2 <b>A. I'm sorry, let me try and read it more</b></p> <p>3 <b>clearly. I'm not seeing it well enough in this print.</b></p> <p>4 <b>Yes. Okay, I see that.</b></p> <p>5 Q. Okay. And do you see the p-value of .7?</p> <p>6 <b>A. .7 had to do with the probability that there</b></p> <p>7 <b>was a difference in the rate of deep versus</b></p> <p>8 <b>superficial infections.</b></p> <p>9 Q. My question is: Do you see the p-value of</p> <p>10 .7?</p> <p>11 <b>A. Yes, I see it.</b></p> <p>12 Q. Is that statistically significant?</p> <p>13 <b>A. No.</b></p> <p>14 Q. Okay. Then it says, "The overall rate of</p> <p>15 deep infection in group 1 was 1 percent (95) compared</p> <p>16 with 2.5 percent in group 2," p-value of .102, do you</p> <p>17 see that?</p> <p>18 <b>A. I do.</b></p> <p>19 Q. Is that statistically significant?</p> <p>20 <b>A. It is not.</b></p> <p>21 Q. Did you take that into account in connection</p> <p>22 with your conclusions in this case that Xarelto is a</p> <p>23 confounding factor for risk of infection?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>
<p style="text-align: right;">Page 150</p> <p>1 <b>me to.</b></p> <p>2 Q. Did you have it in mind when you rendered</p> <p>3 your opinions in this case on June 2nd?</p> <p>4 <b>A. Whether --</b></p> <p>5 <b>The differentiation between the types of</b></p> <p>6 <b>wound infections?</b></p> <p>7 Q. Correct.</p> <p>8 <b>A. I -- I'm sorry, and I'm just backing up. Is</b></p> <p>9 <b>that raised in this document? It would help me to</b></p> <p>10 <b>reconstruct and answer your question.</b></p> <p>11 Q. Well I'm just asking if you had it in mind</p> <p>12 when you --</p> <p>13 <b>A. I'm sure I had it somewhere in mind, but I</b></p> <p>14 <b>don't remember whether it was relevant, that question,</b></p> <p>15 <b>to this article.</b></p> <p>16 Q. Okay. Why don't you take a look at</p> <p>17 intern -- page 523, which is the third page of this</p> <p>18 study, under "Results," and I'd like to direct your</p> <p>19 attention down to the third paragraph starting with</p> <p>20 "Of those patients who returned to theatre,</p> <p>21 microbiology results showed that five of the nine</p> <p>22 (55.5 percent) in group 1 had a deep infection,</p> <p>23 compared with 14 of 22 (63.6 percent) in group 2."</p> <p>24 <b>A. Okay.</b></p> <p>25 Q. And it's got a p-value of .7, do you see</p>	<p style="text-align: right;">Page 152</p> <p>1 <b>A. It's discussed in paragraph 42 and following</b></p> <p>2 <b>in my report.</b></p> <p>3 Q. My question is a little different. Did you</p> <p>4 take that into account in connection with your</p> <p>5 conclusions in this case?</p> <p>6 <b>A. And I'm showing you, yes, I took it into</b></p> <p>7 <b>account --</b></p> <p>8 Q. Okay.</p> <p>9 <b>A. -- in paragraphs 42 and following in my</b></p> <p>10 <b>report.</b></p> <p>11 Q. I think I asked you this before, but in</p> <p>12 connection -- you didn't --</p> <p>13 You didn't actually look at the mathematical</p> <p>14 work Professor Holford did in reanalyzing the McGovern</p> <p>15 data with Jensen; correct?</p> <p>16 MR. GORDON: Objection.</p> <p>17 <b>A. Yes, I did not.</b></p> <p>18 Q. Okay. And to the extent that he used either</p> <p>19 data from Albrecht Exhibit 10 or McGovern Exhibit 16,</p> <p>20 you would be deferring to him as to the</p> <p>21 appropriateness of that; correct?</p> <p>22 <b>A. Yes, I would.</b></p> <p>23 Q. Now I'd like to talk to you a little bit</p> <p>24 about the Hawthorne effect and -- which is contained</p> <p>25 on page 16 of your report. Wouldn't --</p>

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<p style="text-align: right;">Page 153</p> <p>1 Well first of all, wouldn't the Hawthorne</p> <p>2 effect exist in any observational study?</p> <p>3 <b>A. I think it depends upon whether the subjects</b></p> <p>4 <b>are aware of the observation and how intensively the</b></p> <p>5 <b>observation impacts the daily life of those</b></p> <p>6 <b>individuals.</b></p> <p>7 Q. Well do you know whether any of the</p> <p>8 participants in the Reed and McGovern study were</p> <p>9 involved, that there was a study going on?</p> <p>10 <b>A. I -- I understand from the statements that</b></p> <p>11 <b>were made in the citation which I cited -- "citation</b></p> <p>12 <b>which I cited" sounds like a redundancy -- there was</b></p> <p>13 <b>an award given to Northumbria, and in the context of</b></p> <p>14 <b>that they cited the efforts that had gone into it.</b></p> <p>15 <b>There's also description of the change in the</b></p> <p>16 <b>sensibility that was engendered as described by</b></p> <p>17 <b>Gillson and Lowdon or something, and my understanding</b></p> <p>18 <b>is that there was a full-court press to try to change</b></p> <p>19 <b>the behavior of the people, which included changing</b></p> <p>20 <b>clothes and changing the manner in which the clothes</b></p> <p>21 <b>were stored and changing shoes, and a variety of other</b></p> <p>22 <b>things were done, and I think that everybody there was</b></p> <p>23 <b>very aware that there was a problem with infections.</b></p> <p>24 Q. My question was a little different.</p> <p>25 <b>A. Okay. I'm sorry.</b></p>	<p style="text-align: right;">Page 155</p> <p>1 Q. -- which is the Jameson study entitled</p> <p>2 "Wound Complications Following Rivaroxaban</p> <p>3 Administration." This is one of the documents that</p> <p>4 you referenced and opined on in your report; correct?</p> <p>5 <b>A. That's correct.</b></p> <p>6 Q. Okay. In connection with your review, did</p> <p>7 you have in mind a difference or -- between a deep</p> <p>8 joint infection and a superficial or deep tissue</p> <p>9 infection?</p> <p>10 <b>A. I don't think it was defined clearly in this</b></p> <p>11 <b>paper, and so I don't think that I made a decision.</b></p> <p>12 <b>But --</b></p> <p>13 Q. Okay. Would it be important in connection</p> <p>14 with making decisions that a change to Xarelto</p> <p>15 postoperatively as an antithrombotic prophylaxis</p> <p>16 increases the risk of a deep joint infection?</p> <p>17 <b>A. I'm sorry, repeat that.</b></p> <p>18 Q. Sure. Would it be important in connection</p> <p>19 with making decisions in this case that a change in</p> <p>20 Xarelto postoperatively -- postoperatively as an</p> <p>21 antithrombotic prophylaxis increases the risk of a</p> <p>22 deep joint infection as opposed to another kind of</p> <p>23 wound infection?</p> <p>24 <b>A. Would it matter to me? Yes, I would</b></p> <p>25 <b>consider that. I --</b></p>
<p style="text-align: right;">Page 154</p> <p>1 Q. My question was: Do you believe that any of</p> <p>2 the participants' employees understood or were aware</p> <p>3 that there was going to be an observational study</p> <p>4 conducted and published regarding infections in knee</p> <p>5 and hip arthroplasty?</p> <p>6 <b>A. I -- I have --</b></p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question.</p> <p>9 <b>A. I have no idea if anybody at the time knew</b></p> <p>10 <b>because the study was post hoc.</b></p> <p>11 <b>(Discussion off the stenographic record.)</b></p> <p>12 <b>(Exhibit 16 was marked for</b></p> <p>13 <b>identification.)</b></p> <p>14 THE WITNESS: Thank you.</p> <p>15 BY MS. CONLIN:</p> <p>16 Q. I have handed you, sir, what's been marked</p> <p>17 as Borak Deposition Exhibit 16, which is -- not what I</p> <p>18 wanted to give you. Hold on. You can set that aside,</p> <p>19 I'll get back to that.</p> <p>20 <b>(Exhibit 17 was marked for</b></p> <p>21 <b>identification.)</b></p> <p>22 BY MS. CONLIN:</p> <p>23 Q. I have handed you, sir, what's been marked</p> <p>24 as Borak Deposition Exhibit 17, --</p> <p>25 <b>A. Yes.</b></p>	<p style="text-align: right;">Page 156</p> <p>1 <b>Would you point to what you are talking</b></p> <p>2 <b>about in the paper so I understand the context of your</b></p> <p>3 <b>question?</b></p> <p>4 Q. Well I'm just under --</p> <p>5 I'm trying to understand your opinion, sir,</p> <p>6 when you say that the change in -- from rivar -- or</p> <p>7 from trinzaparin to Xarelto creates an increased risk</p> <p>8 of a deep joint infection, that you had paid attention</p> <p>9 in the papers that you were citing as to differences</p> <p>10 between, for example, a superficial wound or a deep</p> <p>11 wound infection and a deep joint infection.</p> <p>12 <b>A. I'm sorry, I -- I cited this paper for a</b></p> <p>13 <b>different reason, not to suggest what you are asking.</b></p> <p>14 <b>I cited it because Dr. Samet had cited it, and Dr.</b></p> <p>15 <b>Samet had cited it as evidence that it did not create</b></p> <p>16 <b>a difference.</b></p> <p>17 Q. My question was: When you opine that a</p> <p>18 change from trinzaparin to Xarelto creates an</p> <p>19 increased risk of deep joint infection, did you pay</p> <p>20 attention in the papers that you were citing as to the</p> <p>21 differences between, for example, superficial wound or</p> <p>22 deep wound or a deep joint infection?</p> <p>23 <b>A. Let me answer, yes, I was aware of the</b></p> <p>24 <b>difference.</b></p> <p>25 Q. Do you think that you can extrapolate from</p>

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<p>1 papers regarding superficial wound infections to a 2 deep joint infection?</p> <p>3 <b>A. I am not a nosocomial infection expert. I</b> 4 <b>was looking at a very specific paper, not generalizing</b> 5 <b>from it. It was a paper that was cited for a</b> 6 <b>particular purpose. I was responding to that.</b></p> <p>7 Q. Can you answer my question?</p> <p>8 <b>A. Ask the question again.</b></p> <p>9 Q. Sure. Do you think that you can extrapolate 10 from papers regarding superficial wound infections to 11 deep joint infections in connection with what might be 12 a confounder or not?</p> <p>13 <b>A. I -- I didn't. I'm not sure that I did that</b> 14 <b>and I'm not sure that you can do that.</b></p> <p>15 Q. Okay. You'd agree with me that there's a 16 difference between a -- a -- a superficial surgical- 17 site infection and a deep joint infection; correct?</p> <p>18 <b>A. I understand that there is a difference.</b></p> <p>19 Q. Okay. Changing the dressings or a change in 20 protocol on changing the dressings might affect a 21 superficial surgical-site infection but not 22 necessarily impact a deep joint infection.</p> <p>23 <b>A. Or might affect both, yes.</b></p> <p>24 Q. Do you know whether it could affect both?</p> <p>25 <b>A. I thought I had seen comments by Dr. Reed</b></p>	<p>1 increase in infectious microbes in the air can affect 2 your ability to get a deep joint infection; correct?</p> <p>3 <b>A. I said I don't -- I don't have an opinion</b> 4 <b>about that.</b></p> <p>5 Q. Okay.</p> <p>6 <b>A. That's correct.</b></p> <p>7 Q. So if it's on the skin, you have an opinion 8 about it, if it's in the air, you don't; correct?</p> <p>9 <b>A. The answer is yes, because the available</b> 10 <b>data are different.</b></p> <p>11 MS. CONLIN: Okay. All right. Why don't we 12 stop here for lunch.</p> <p>13 THE REPORTER: Off the record, please. 14 (Luncheon recess taken.)</p> <p>15 16 17 18 19 20 21 22 23 24 25</p>
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<p>1 <b>indicating that a change in dressing affected that</b> 2 <b>outcome, but I can't point to where it was other than</b> 3 <b>maybe a deposition.</b></p> <p>4 Q. So it's your understanding that Dr. Reed 5 said that a change in dressing or change in protocol 6 in dressings could affect a deep joint infection?</p> <p>7 <b>A. I believe that is my remembrance, but it may</b> 8 <b>not be correct. I didn't focus on it.</b></p> <p>9 Q. Well you talked about changes in the 10 protocol; right?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. And skin preparation; right?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. Okay. Do you think that a change in skin 15 preparation can have an impact on a deep joint 16 infection?</p> <p>17 <b>A. Absolutely.</b></p> <p>18 Q. Okay. How so?</p> <p>19 <b>A. Reducing the number of bacteria on the skin</b> 20 <b>reduces the likelihood of followup -- of -- of</b> 21 <b>infection postoperatively.</b></p> <p>22 Q. Okay. So having less bacteria on your skin 23 can lower your risk of a deep joint infection.</p> <p>24 <b>A. I think there's evidence of that.</b></p> <p>25 Q. Okay. But you don't know whether having an</p>	<p>1 AFTERNOON SESSION</p> <p>2 BY MS. CONLIN:</p> <p>3 Q. If the change in antithrombotic prophylaxis 4 is not a confounder, in other words, meaning there's 5 no association as -- as you've described it, doing a 6 remix of the Jensen data and the McGovern data would 7 not make sense in that case; right?</p> <p>8 MR. GORDON: Object to the form of the 9 question.</p> <p>10 <b>A. You asked me first a hypothetical, saying if</b> 11 <b>there were none.</b></p> <p>12 Q. Yup.</p> <p>13 <b>A. Okay. And then when you say the remix, are</b> 14 <b>you referring to what Professor Holford did?</b></p> <p>15 Q. Correct.</p> <p>16 <b>A. I think that it would still have merit given</b> 17 <b>the fact that the followup period in the Jensen study</b> 18 <b>was probably too short because of the well-recognized</b> 19 <b>delay in the manifestation of infections.</b></p> <p>20 Q. The hypothetical is is that the change in -- 21 there's no association between a change in 22 antithrombotic prophylaxis and infection. If that's 23 the case, there would be no reason for Dr. Holford to 24 attempt to remix the data from Jensen; correct?</p> <p>25 <b>A. Correct, other than to question whether that</b></p>

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<p style="text-align: right;">Page 161</p> <p>1 <b>assumption was correct or incorrect.</b>  2 <b>(Exhibit 18 was marked for</b>  3 <b>identification.)</b>  4 BY MS. CONLIN:  5 Q. I've handed you what's been marked as Borak  6 Exhibit 18, which was -- is an excerpt from the  7 deposition of Dr. Reed, and I'd like to direct your  8 attention to internal page 215 of this exhibit. And  9 this is relating to the Reed study, I'll represent to  10 you, the Reed study on Xarelto that we just looked at  11 and was marked as Exhibit 19. If we can take a look  12 at page 215 --  13 Let me -- let me just make sure I gave you  14 the right exhibit number. Yeah, that's it.  15 <b>A. Can -- can we, just for avoiding confusion,</b>  16 <b>agree that what you were referring to as the Reed</b>  17 <b>study is the Jensen study?</b>  18 Q. Sure. And I apologize for that.  19 <b>A. No, no, no, no, no. I -- I'm not trying to</b>  20 <b>make it harder, --</b>  21 Q. All right.  22 <b>A. -- I'm trying to make it clearer.</b>  23 Q. So with regard to this testimony on page  24 215, internal page 215 of Exhibit 18, they're  25 referencing the Jensen study, and I'd like to direct</p>	<p style="text-align: right;">Page 163</p> <p>1 looking at the date of the McGovern paper, that we can  2 exclude xarelto as a confounding factor for infection  3 rates?"  4 MS. CONLIN: He's not an author on that, Mr.  5 Gordon.  6 THE WITNESS: Mr. -- Dr. Reed is.  7 MS. CONLIN: On the Jameson paper?  8 MR. GORDON: Yes.  9 THE WITNESS: He's the last author.  10 MS. CONLIN: Okay.  11 MR. GORDON: He's a senior author.  12 Q. Okay. So let me start over. With reference  13 to the Jameson paper, the testimony went as follows:  14 "So would you agree with me that based on  15 this study, that you are an author of, that looking at  16 the date of the McGovern paper, that we can now  17 exclude xarelto as a confounding factor for infection  18 rates?"  19 "Answer: I think that's what this paper  20 says."  21 Do you see that?  22 <b>A. I do see that.</b>  23 Q. And you disagree with Dr. Reed, the author  24 of the Jameson -- one of the authors of the Jameson  25 study; correct?</p>
<p style="text-align: right;">Page 162</p> <p>1 your attention down to line --  2 MR. GORDON: Jan, I -- I -- I can't believe  3 you're trying to sandbag him with that. He's not  4 talking about the Jensen study here. And I -- I --  5 I'm assuming you don't know. He's talking about the  6 Jameson study.  7 MS. CONLIN: Oh, okay. I stand corrected.  8 As you know me, Mr. Gordon, I wouldn't do that to a  9 witness, so --  10 MR. GORDON: And that's why I said it that  11 way.  12 MS. CONLIN: All right. Thank you. Yeah.  13 Okay.  14 Q. Do you see the testimony on 215, starting at  15 line 14 --  16 And I stand corrected. It is in connection  17 with the Jameson study which is -- we also marked this  18 morning as Exhibit 17.  19 MR. GORDON: Seventeen.  20 Q. Okay? And do you see it says:  21 "So based on this study of 12,000 patients,  22 I would say that there was no effect on return to  23 surgery from infection.  24 "Question: So would you agree with me that  25 based on this study, that you are an author of, and</p>	<p style="text-align: right;">Page 164</p> <p>1 <b>A. Yes.</b>  2 Q. And you disagree with his conclusions as it  3 relates to the Jensen study, of which he is also an  4 author; correct?  5 <b>A. We -- I --</b>  6 <b>I think so, but I'm not sure which</b>  7 <b>conclusion you're referring to.</b>  8 Q. That Xarelto was not a confounding factor in  9 connection with the McGovern study.  10 <b>A. It's two separate issues. I agree with you</b>  11 <b>on both of those. I disagree with Dr. Reed.</b>  12 Q. Okay.  13 <b>A. You're not interested in why?</b>  14 Q. Actually, I am. Go ahead and tell me why  15 you disagree.  16 <b>A. Well I think that in the Jensen study the</b>  17 <b>2.5-to-one ratio of deep infection increase is</b>  18 <b>indication of confounding. The only conclusion that</b>  19 <b>supports that it's not important is that it's</b>  20 <b>statistically not significant, and when re-evaluated</b>  21 <b>it was statistically significant. That is Dr.</b>  22 <b>Holford's re-evaluation.</b>  23 <b>The Jameson study provides a totally</b>  24 <b>different thing. It contains contradictory internal</b>  25 <b>information that I believe it is not useful, and part</b></p>

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<p style="text-align: right;">Page 165</p> <p>1 of it is that while it does at one place say that the  2 combined data did not have a statistically significant  3 increase -- and that's in a table on page 1556 --  4 however, there were these other difficulties. One of  5 them is that the numbers don't add up. It -- it does  6 not make sense, the paper, the data do not make sense.  7 And the other is that the authors clearly state that  8 they were unable to differentiate from this pooled  9 data set between return to theater for infection  10 versus return for other wound complications, and they  11 just pooled them.</p> <p>12 Now the point I made in my report -- and I  13 just point out so you understand -- I'm -- what I'm  14 saying is the Jameson study isn't usable, and I point  15 to the fact that in Table 2 on what you refer to as  16 internal 1556, there is a count of total wound  17 complications and underneath that there is a list of  18 those that were managed non-operatively and those that  19 returned to surgery for infection, and when you add  20 them up, it does not square. There are too many  21 cases. The numbers are not correct.</p> <p>22 Q. Okay. So that's based on your view that you  23 couldn't understand what was going on in that study,  24 but you don't agree with the author of the study who  25 says in his mind this created a conclusion that</p>	<p style="text-align: right;">Page 167</p> <p>1 of your report, --</p> <p>2 A. Yes.</p> <p>3 Q. -- and I'd like to talk to you about your  4 section entitled "...Skin Preparation."</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And it's your opinion that the --  7 Is it your opinion that the change in skin  8 preparation protocol during the McGovern study period  9 was a confounder?</p> <p>10 A. It probably was. There's no evidence to say  11 "yes" or "no," but it is one that should have been  12 considered. I think it was likely to be.</p> <p>13 Q. Okay. So without evidence, you're okay  14 saying there is an association between the change in  15 skin protocol and the risk of infection, is that  16 right, at least as it relates to skin preparation?</p> <p>17 A. My sen -- my --</p> <p>18 My statement was to the extent that use of  19 chlorhexidine reduced infections would be -- only  20 reduce the rate in the non-FAW cases, thereby wrongly  21 suggesting a benefit. In that case, it would have  22 been a confounder.</p> <p>23 Q. My -- my question was -- okay.</p> <p>24 My question was: So you're saying that  25 there's an association between the change in skin</p>
<p style="text-align: right;">Page 166</p> <p>1 Xarelto was not a confounding factor in McGovern.</p> <p>2 A. Yes, I believe these data did not support  3 that conclusion.</p> <p>4 Q. Now you mentioned in that last answer that  5 you thought the authors didn't discriminate between  6 re -- repeat surgical-wound irrigation for infection  7 and surgery for hematoma; correct?</p> <p>8 A. Yes.</p> <p>9 Q. That -- that involves the procedure, not the  10 detection of a DJI; correct?</p> <p>11 A. They group them together.</p> <p>12 Q. Well no. It just --</p> <p>13 They grouped them together for the purposes  14 of the surgery, not whether there were infections.</p> <p>15 A. Yes, yes, yes.</p> <p>16 Q. Okay.</p> <p>17 A. And there's no data to conclude about  18 infections because they were grouped together. They  19 do not have a separate list. To the contrary, what  20 they say was -- if I can find it --</p> <p>21 I'm sorry, let me -- I have it in my report.  22 If I find it, it will save rather than looking in --</p> <p>23 Q. I read it in your report. Let's move on.</p> <p>24 A. Okay.</p> <p>25 Q. If we can direct your attention to page 14</p>	<p style="text-align: right;">Page 168</p> <p>1 protocol and the risk of infection, at least as it  2 relates to skin preparation; correct?</p> <p>3 A. I -- I think that that is correct.</p> <p>4 Q. Okay. And in connection with this you cite  5 Dr. Reed's testimony; right? Quote, "If your surgeon  6 is still using iodine plus alcohol then there is a  7 very robust study that shows they could do better;"  8 correct?</p> <p>9 A. Correct, I did cite that.</p> <p>10 Q. So in connection with this you're relying on  11 Dr. Reed; correct?</p> <p>12 A. I'm pointing to Dr. Reed agreeing with me,  13 yes.</p> <p>14 Q. Right. You're relying on it.</p> <p>15 A. I don't know that I specifically relied upon  16 it, but I cited it.</p> <p>17 Q. Well you said earlier in your report that if  18 you cited it, you relied on it.</p> <p>19 A. No, no. I appreciate what you're saying. I  20 would have reached the same conclusion without Dr.  21 Reed's opinion.</p> <p>22 Q. Okay. But you took the time to put Dr.  23 Reed's testimony in on this; correct?</p> <p>24 A. I did.</p> <p>25 Q. Okay. And then you say, "Use of</p>

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<p style="text-align: right;">Page 169</p> <p>1 chlorhexidine alcohol has been reported to reduce SSI</p> <p>2 by up to 40 percent compared to po -- povidone-</p> <p>3 iodine" --</p> <p>4 Did I say that right?</p> <p>5 <b>A. No, but it's close enough.</b></p> <p>6 Q. How do you say that?</p> <p>7 <b>A. Povidine.</b></p> <p>8 Q. Povidone-iodine.</p> <p>9 <b>A. Povidone.</b></p> <p>10 Q. Povidone.</p> <p>11 <b>A. I actually normally put a -- incorrectly put</b></p> <p>12 <b>an "r" in the word. That's okay, I will take however</b></p> <p>13 <b>you say it.</b></p> <p>14 Q. -- "povidone-iodine and it reduced</p> <p>15 infections related to vascular catheters by 49</p> <p>16 percent." Correct?</p> <p>17 <b>A. Correct.</b></p> <p>18 Q. That didn't involve deep joint infections,</p> <p>19 correct, --</p> <p>20 <b>A. No, it did not.</b></p> <p>21 Q. -- in arthroplastic or hip -- hip and knee</p> <p>22 replacements; correct?</p> <p>23 <b>A. Correct.</b></p> <p>24 Q. And you also cite in that sentence to</p> <p>25 reference 33, which is a Darouiche reference; correct?</p>	<p style="text-align: right;">Page 171</p> <p>1 <b>A. I do.</b></p> <p>2 Q. It says:</p> <p>3 -- "but not against organ-space infections."</p> <p>4 Do you see that?</p> <p>5 <b>A. I do.</b></p> <p>6 Q. 4.4 percent to 4.5 percent; correct?</p> <p>7 <b>A. Correct.</b></p> <p>8 Q. Okay. So how is it that this study supports</p> <p>9 your conclusion that the change in skin preparation</p> <p>10 during the McGovern period was a confounder?</p> <p>11 <b>A. I think it provides evidence of decreased</b></p> <p>12 <b>wound infections, and I believe wound infections lead</b></p> <p>13 <b>to, mechanistically, deep infections and conceivably</b></p> <p>14 <b>joint infections.</b></p> <p>15 Q. How did you rely on this study when the</p> <p>16 authors found virtually no change in deep joint</p> <p>17 infections --</p> <p>18 MR. GORDON: Object to the form --</p> <p>19 Q. -- between the two protocols?</p> <p>20 MR. GORDON: Object to the form,</p> <p>21 mischaracterizes the evidence.</p> <p>22 <b>A. It provides evidence of decreased deep wound</b></p> <p>23 <b>infections. I believe that is a risk for the joint</b></p> <p>24 <b>infections.</b></p> <p>25 Q. I'm sorry, can you say what you said again?</p>
<p style="text-align: right;">Page 170</p> <p>1 <b>A. Correct.</b></p> <p>2 Q. Let me pull that out for you.</p> <p>3 (Exhibit 19 was marked for</p> <p>4 identification.)</p> <p>5 THE WITNESS: Thank you.</p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you, sir, what's been marked as</p> <p>8 Deposition Exhibit 19, which is an article entitled</p> <p>9 "Chlorhexidine-Alcohol versus Povidone-Iodine for</p> <p>10 Surgical-Site Antisepsis." Do you see that?</p> <p>11 <b>A. I do.</b></p> <p>12 Q. And the lead author on this is Dr.</p> <p>13 Darouiche; --</p> <p>14 <b>A. Correct.</b></p> <p>15 Q. -- correct? And I'd like --</p> <p>16 And this was something you relied on to say</p> <p>17 that the change in skin preparation during the</p> <p>18 McGovern period was a confounder; correct?</p> <p>19 <b>A. Correct.</b></p> <p>20 Q. So let's take a look at the results section</p> <p>21 on this. It says about midway down, "Chlorhexidine-</p> <p>22 alcohol was significantly more protective than</p> <p>23 povidone-iodine against both superficial incisional</p> <p>24 infections and deep incisional infections" --</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 172</p> <p>1 <b>A. I said it decreases deep infections, and I</b></p> <p>2 <b>believe that's a risk for joint infections. But I</b></p> <p>3 <b>would defer on that opinion probably to Dr. Wenzel.</b></p> <p>4 Q. How -- how does a microbe from the skin get</p> <p>5 onto an implant?</p> <p>6 <b>A. It depends on the circumstance. I think</b></p> <p>7 <b>that, for example, it can swim through the tissues.</b></p> <p>8 Q. So it starts on the skin and decides it</p> <p>9 wants to land on the implant and it swims down?</p> <p>10 <b>A. I don't know whether it makes a conscious</b></p> <p>11 <b>decision, but I think that there is a spread that can</b></p> <p>12 <b>occur, yes.</b></p> <p>13 Q. Okay. But you don't think that it can be</p> <p>14 floating in the air and drop down, it's got to swim</p> <p>15 through the tissue?</p> <p>16 <b>A. I don't know that. I've said only that I</b></p> <p>17 <b>see no evidence that the air dispersion results in</b></p> <p>18 <b>increased infections.</b></p> <p>19 Q. Okay. And in your mind there is -- that</p> <p>20 if -- that if something decreases a deep tissue</p> <p>21 infection, it should also decrease the risk of a deep</p> <p>22 joint infection?</p> <p>23 <b>A. I think it's reasonable to me, but it's not</b></p> <p>24 <b>my area of expertise and it's not an expert opinion</b></p> <p>25 <b>that I'm rendering.</b></p>

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<p>1 Q. Okay. Well you'd agree with me that looking 2 at the Darouiche article suggests that there is no 3 difference for deep joint infections between these two 4 protocols. 5 MR. GORDON: Jan, again I'm going to assume 6 you're -- you're -- you're -- you're not doing this 7 intentionally. Darouiche says nothing about joint 8 infections. 9 Q. What do you understand -- 10 MR. GORDON: It was clean contaminated 11 surgery. 12 Q. What do -- what do you think organ-space 13 infections is? 14 <b>A. I would have assumed it was things like</b> 15 <b>intrapleural infections or peritoneal infections. But</b> 16 <b>your point is well taken. I can't define that term</b> 17 <b>right now.</b> 18 Q. Okay. Now what was the change in skin 19 preparation protocol during McGovern? 20 <b>A. The adoption of chlorhexidine as opposed to</b> 21 <b>povidone-iodine, which was effected in October of</b> 22 <b>2010.</b> 23 Q. You reference here that the "CDC found 24 'high-quality evidence suggested a benefit of CHG- 25 alcohol [chlorohex -- chlorhexidine gluconate-alcohol]</p>	<p>1 "There is also evidence that the combination of MSSA 2 screening and chlorhexidine was complementary, 3 resulting in a five-fold reduction in deep SSI 4 compared -- compared to the placebo." Do you see 5 that? 6 <b>A. Yes.</b> 7 Q. Okay. And let me pull that out for you. 8 (Exhibit 20 was marked for 9 identification.) 10 BY MS. CONLIN: 11 Q. I have handed you what's been marked as 12 Borak Exhibit 20, which is the Bode reference which 13 supports your statement in your report that there's 14 also evidence that a combination of MSSA screening and 15 chlorhexidine was complementary, resulting in a 16 five-fold reduction in deep SSI compared to placebo; 17 correct? 18 <b>A. Yes.</b> 19 Q. Okay. Now what was the placebo that was 20 used in this study? 21 <b>A. I would have to look back.</b> 22 <b>They describe it as "placebo," which I</b> 23 <b>assume would -- may have been inactive, but I do not</b> 24 <b>know. I don't see a description of --</b> 25 MR. GORDON: It's on page 11, the</p>
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<p>1 as compared with aqueous iodophor." Do you see that? 2 <b>A. I do.</b> 3 Q. Okay. There was no point in time during the 4 McGovern period where aqueous iodophor was being used. 5 <b>A. I believe that's the povidone-iodine analog.</b> 6 Q. But it wasn't the same. 7 <b>A. It may not have been exactly the same.</b> 8 <b>There were several variants of the iodine that was</b> 9 <b>used.</b> 10 Q. Okay. And you think that a -- that even 11 though there -- well let me strike that and ask it a 12 different way. 13 If it wasn't aqueous iodophor that was ever 14 used for McGovern, what relevance if any does the CDC 15 findings that you've stated here have? 16 <b>A. This statement that chlorhexidine, in the</b> 17 <b>views of CDC, was preferable to what was then the most</b> 18 <b>used iodine for skin treatment was meaningful to me.</b> 19 Q. So if something is slightly different, you 20 still think it's okay to use it and extrapolate to 21 that in connection with your conclusions in this case? 22 <b>A. I thought that there was high-quality</b> 23 <b>evidence that this chlorhexidine was useful. But I</b> 24 <b>understand your question about the direct comparison.</b> 25 Q. Then you also cite here -- or you state,</p>	<p>1 randomization. 2 MS. CONLIN: You don't need to help him. 3 I'm trying to get his understanding, Mr. Gordon, of 4 what he had in mind when he -- 5 MR. GORDON: Jan, we can -- 6 If you -- if you want to know what was in 7 one of the dozens of articles he cited, you can either 8 take the time and he'll read through it all, or I -- 9 You know, sorry, I won't point him to it. 10 But just so I understand, next time he'll -- he'll -- 11 he'll read it in its entirety. 12 <b>A. Okay. So it's the "Placebo soap and</b> 13 <b>ointment were identical to the active treatment except</b> 14 <b>for the active ingredients," so it was inactive.</b> 15 Q. So the placebo didn't have any antimicrobial 16 effect; correct? 17 <b>A. That's my understanding.</b> 18 Q. Okay. So do you think it's appropriate to 19 rely on a placebo study for your conclusion that the 20 change in skin preparation during the McGovern study 21 was a confounder? 22 <b>A. I think it reflects the fact that the two</b> 23 <b>were interactive and complementary; that is, the</b> 24 <b>mech -- the chlorhexidine and the screening. But I do</b> 25 <b>understand that this is a comparison against placebo.</b></p>

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<p style="text-align: right;">Page 177</p> <p>1 Q. Right. And so did you see anything that had</p> <p>2 a comparison that showed a statistical difference</p> <p>3 between the skin preparation used at the beginning of</p> <p>4 the McGovern study and the skin preparation that was</p> <p>5 implemented in October 2010?</p> <p>6 <b>A. The iodophor is the only head-to-head that I</b></p> <p>7 <b>can point to here at this moment.</b></p> <p>8 Q. Okay. And you know that wasn't the exact</p> <p>9 one; correct?</p> <p>10 <b>A. I think it was not exact. I could look it</b></p> <p>11 <b>up again. I know I looked at it at one time.</b></p> <p>12 Q. Do you have any evidence as you sit there --</p> <p>13 <b>A. As I sit here today --</b></p> <p>14 Q. -- of a pub -- of a published study that</p> <p>15 suggests a material difference between the two skin-</p> <p>16 preparation protocols and a risk of a deep joint</p> <p>17 infection?</p> <p>18 <b>A. I don't know that I can point to one now,</b></p> <p>19 <b>but this again is something to which I will defer to</b></p> <p>20 <b>Dr. Wenzel.</b></p> <p>21 Q. Okay. But without evidence, you're still</p> <p>22 comfortable opining that there is an association, at</p> <p>23 least as it relates to skin preparation; correct?</p> <p>24 <b>A. I think I was carefully nuanced in my</b></p> <p>25 <b>statement, which was "To the extent that use of</b></p>	<p style="text-align: right;">Page 179</p> <p>1 Stirewalt.</p> <p>2 (Holford Exhibit 9 handed to the witness.)</p> <p>3 THE WITNESS: Thank you.</p> <p>4 Q. I've handed you what was marked as Holford</p> <p>5 Deposition Exhibit 9, which is the Darouiche study</p> <p>6 entitled "Association of Airborne Microorganisms in</p> <p>7 the Operating Room With Implant Infections: A</p> <p>8 Randomized Controlled Trial." Do you see that?</p> <p>9 <b>A. Yes, I do.</b></p> <p>10 Q. And do you -- do you agree with me that an</p> <p>11 RCT is, in terms of the pecking order of evidence that</p> <p>12 you rely on in an epidemiologic study, a step above</p> <p>13 observational studies?</p> <p>14 <b>A. Generally, if it's well done.</b></p> <p>15 Q. Okay. And you see it says the objective is</p> <p>16 "To evaluate the association" --</p> <p>17 By the way, do you know if this -- this is</p> <p>18 the same Dr. Darouiche that you relied on in</p> <p>19 connection with your opinions regarding skin</p> <p>20 preparation; --</p> <p>21 <b>A. I'm aware.</b></p> <p>22 Q. -- correct?</p> <p>23 MR. GORDON: Dick, your --</p> <p>24 It (referring to realtime screens) stopped.</p> <p>25 I don't -- I don't care for myself, but I just want</p>
<p style="text-align: right;">Page 178</p> <p>1 <b>chlorhexidine reduced infections, it would be a</b></p> <p>2 <b>confounder."</b></p> <p>3 Q. But my point is is you -- you said at the</p> <p>4 beginning of this module that we started that you do</p> <p>5 believe it's a confounder, but you'll agree with me</p> <p>6 that you don't have any evidence that the skin --</p> <p>7 change in skin preparation during the McGovern period</p> <p>8 was --</p> <p>9 <b>A. I do not have a direct comparison --</b></p> <p>10 Q. Right.</p> <p>11 <b>A. -- to offer you today.</b></p> <p>12 Q. Right. But you're still comfortable saying</p> <p>13 there's an association.</p> <p>14 <b>A. I think that there might be.</b></p> <p>15 Q. Okay. There might be?</p> <p>16 <b>A. I don't have any evidence to ful -- complete</b></p> <p>17 <b>the last sentence, which I gave you before, which was</b></p> <p>18 <b>that if there was a reduction from the chlorhexidine,</b></p> <p>19 <b>it would be a confounder, and I don't have any field</b></p> <p>20 <b>data in the McGovern study showing that it wasn't.</b></p> <p>21 Q. All right. I'd like to go to your next</p> <p>22 section --</p> <p>23 Actually, let's go back to page 12.</p> <p>24 MS. CONLIN: Actually, before we go there,</p> <p>25 can you pull out Exhibit 9 from yesterday, Mr.</p>	<p style="text-align: right;">Page 180</p> <p>1 you to -- if that means your computer screwed up, I</p> <p>2 don't want to --</p> <p>3 THE REPORTER: Let's go off the record,</p> <p>4 please.</p> <p>5 (Discussion off the record.)</p> <p>6 BY MS. CONLIN:</p> <p>7 Q. So I take it during the break you did some</p> <p>8 internet searching in connection with your iodine --</p> <p>9 aqueous iodophor; is that right?</p> <p>10 <b>A. Correct.</b></p> <p>11 Q. And that's something that you've learned</p> <p>12 since you've been sitting here?</p> <p>13 <b>A. It's something I affirmed in my mind since I</b></p> <p>14 <b>was sitting here after your -- you took a break.</b></p> <p>15 Q. Yeah. Go ahead.</p> <p>16 <b>A. Yeah. It's the same thing as povidone-</b></p> <p>17 <b>iodine.</b></p> <p>18 Q. And in connection with your CDC statement</p> <p>19 there, do you know whether the CDC was referencing</p> <p>20 wound infections generally versus deep joint</p> <p>21 infections?</p> <p>22 <b>A. I can't tell you that right now.</b></p> <p>23 Q. Okay. So back to the point before the</p> <p>24 break: As you sit here today, you don't know of any</p> <p>25 published study that suggests a change -- the change</p>

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<p style="text-align: right;">Page 181</p> <p>1 in skin preparation during the McGovern period</p> <p>2 creates -- or is a confounder associated with risk of</p> <p>3 infection; correct?</p> <p>4 <b>A. I cannot tell you whether article 33</b></p> <p>5 <b>specifically looked at that, no, not now as we are</b></p> <p>6 <b>sitting here.</b></p> <p>7 Q. Now if we can turn to Holford Deposition</p> <p>8 Exhibit 9, the article entitled "Association of</p> <p>9 Airborne Micronis -- Microorganisms in the Operating</p> <p>10 Room With Implant Infections...", you see -- I think</p> <p>11 we talked about this before the break -- that Dr.</p> <p>12 Darouiche is the same doctor who you cited in</p> <p>13 connection -- his study in connection with your skin-</p> <p>14 preparation section of your report; correct?</p> <p>15 <b>A. That's correct.</b></p> <p>16 Q. And the objective of this article is "To</p> <p>17 evaluate the association of airborne colony-forming</p> <p>18 units (CFU) at incision sites during implantation of</p> <p>19 prostheses with incidence of either incisional or</p> <p>20 prosthesis-related surgical site infections;" correct?</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. Okay. And if we can take a look at the last</p> <p>23 page of this, the "In conclusion...", Drs. Darouiche</p> <p>24 and the other study authors of this randomized</p> <p>25 clinical trial write, quote, "In conclusion, our</p>	<p style="text-align: right;">Page 183</p> <p>1 Q. Right. And you hadn't seen the fact that</p> <p>2 the manufacturer of the Bair Hugger warned at the FDA</p> <p>3 of the risk of airborne contamination; correct?</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question.</p> <p>6 <b>A. I -- if you'll --</b></p> <p>7 <b>I think you're referring to that five oh --</b></p> <p>8 <b>512(k) or something?</b></p> <p>9 Q. 510(k), yes.</p> <p>10 <b>A. I think there was a statement there that</b></p> <p>11 <b>there was no evidence of infections resulting</b></p> <p>12 <b>therefrom.</b></p> <p>13 Q. I didn't ask you about that. Can you answer</p> <p>14 my question?</p> <p>15 <b>A. Ask the question again.</b></p> <p>16 Q. Sure.</p> <p>17 MS. CONLIN: Could you read it back, Mr.</p> <p>18 Court Reporter.</p> <p>19 (Record read by the court reporter.)</p> <p>20 <b>A. I guess that was a statement in that paper.</b></p> <p>21 Q. I'd like to turn back now to page 12 of your</p> <p>22 report, the prophylactic antibiotics. And you</p> <p>23 understand that during the McGovern period there was a</p> <p>24 change in Gentamicin to Gentamicin plus Teicoplanin?</p> <p>25 <b>A. Yes.</b></p>
<p style="text-align: right;">Page 182</p> <p>1 results indicate that CFU contamination of air at the</p> <p>2 incision site is a risk factor for implant but not</p> <p>3 incisional infections. CFU contamination is related</p> <p>4 to the particulate density in the air at the incision</p> <p>5 site, and both CFU and particulate density are a</p> <p>6 function of the number of people in the operating</p> <p>7 room. Limiting airborne CFU contamination at the</p> <p>8 incision site can be expected to lower implant</p> <p>9 infection risk." Do you see that?</p> <p>10 <b>A. I see that.</b></p> <p>11 Q. And you didn't opine on this particular</p> <p>12 article or challenge the validity of the RCT that is</p> <p>13 described in Holford Deposition Exhibit 9; correct?</p> <p>14 <b>A. This paper? Yes, I did not. This paper</b></p> <p>15 <b>does not deal with Bair Hugger.</b></p> <p>16 Q. Well it deals with CFUs in the air near the</p> <p>17 implant; correct?</p> <p>18 <b>A. Yes. Yes.</b></p> <p>19 Q. Okay. And you've already stated you don't</p> <p>20 have an opinion whether Bair Hugger increases CFUs in</p> <p>21 the air at the incisional site; correct?</p> <p>22 MR. GORDON: Objection, mischaracterizes his</p> <p>23 testimony.</p> <p>24 <b>A. I said I did not have such an expert</b></p> <p>25 <b>opinion.</b></p>	<p style="text-align: right;">Page 184</p> <p>1 Q. Okay. Can I refer to the Gentamicin period</p> <p>2 as Gen and the Gentamicin plus Teicoplanin as GenTeic?</p> <p>3 <b>A. Sure.</b></p> <p>4 Q. Okay. And you'll understand what I'm</p> <p>5 referring to.</p> <p>6 <b>A. I think so.</b></p> <p>7 Q. And I take it that you found the change in</p> <p>8 prophylactic antibiotics to be a confounder; am I</p> <p>9 right?</p> <p>10 <b>A. It appeared to confound, yes.</b></p> <p>11 Q. Okay. Meaning that there is an association</p> <p>12 between the change in the -- in -- from Gen to GenTeic</p> <p>13 and risk of infection; correct?</p> <p>14 <b>A. Yes. And they were differentially -- the</b></p> <p>15 <b>antibiotics were differentially associated with the</b></p> <p>16 <b>two different warming units.</b></p> <p>17 Q. What do you mean by "warming units?"</p> <p>18 <b>A. Bair Hugger versus Hot Dog.</b></p> <p>19 Q. Oh, okay.</p> <p>20 What investigation did you do to ascertain</p> <p>21 that, with respect to prosthetic joint infections --</p> <p>22 not just infections in general but prosthetic joint</p> <p>23 infections since that's what we're talking about --</p> <p>24 that a change from Gen to GenTeic would be a</p> <p>25 confounder?</p>

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<p style="text-align: right;">Page 185</p> <p>1       <b>A. Well I read a lot of literature and I</b>  2       <b>evaluated, as I could, the papers that were put in</b>  3       <b>front of me by my search on McGowan -- McGovern, and I</b>  4       <b>looked at statements from Dr. Reed and others that</b>  5       <b>seemed to be that there was evidence that there was an</b>  6       <b>increase in infections when Gentamicin was used alone</b>  7       <b>and a decrease when Teicoplanin was added.</b>  8       Q. Well if anything, then, GenTeic would  9       increase the risk of deep joint infections in Hot Dog;  10       correct?  11       <b>A. Why would that be?</b>  12       Q. Well did you -- did you analyze whether  13       there was an increase or decrease in infections  14       related to the Gen versus GenTeic period, or did you  15       rely on Professor Holford for that analysis?  16       <b>A. I -- I didn't independently review any</b>  17       <b>arithmetic calculations, if that's your question.</b>  18       Q. Okay. Well you understand that during the  19       Hot Dog period GenTeic was used; correct?  20       <b>A. Correct.</b>  21       Q. Exclusively. All right.  22       Did you understand that, based on Professor  23       Holford's analysis, patients who received Gen had a  24       deep joint infection rate of 1.92 while patients who  25       received GenTeic had a 3.13 percent infection rate?</p>	<p style="text-align: right;">Page 187</p> <p>1       <b>describe it, but yes, I think in effect that's what</b>  2       <b>happens.</b>  3       Q. And you can't deliver that much antibiotic  4       to a patient that can penetrate that, and that's one  5       of the reasons why deep joint infections take a while  6       to show up; correct?  7       MR. GORDON: Same objection.  8       <b>A. I don't think -- I don't think that's why it</b>  9       <b>takes a while for them to show up, but --</b>  10       Q. Have you seen articles that have concluded  11       that the benefits of prophylactic antibiotics in  12       reducing infection rates after clean surgeries are  13       unclear?  14       MR. GORDON: Object to the form of the  15       question.  16       <b>A. I don't know that I've seen that.</b>  17       Q. Okay. That wasn't something you came  18       across?  19       <b>A. I don't remember it.</b>  20       Q. Well how did you go about making the  21       decision that the change in prophylactic antibiotics  22       would have a material effect on risk of infection in a  23       prosthetic joint?  24       MR. GORDON: Object to the form of the  25       question.</p>
<p style="text-align: right;">Page 186</p> <p>1       <b>A. Would you point me to where those numbers</b>  2       <b>are found?</b>  3       Q. I'm just asking if you know.  4       <b>A. I --</b>  5       <b>Off the top of my head, I don't remember the</b>  6       <b>numbers.</b>  7       Q. Okay. So how can you determine that  8       something is a confounder if you didn't even look at  9       that issue as it relates to the infection rates  10       between the two?  11       <b>A. On the numerical thing, I relied upon Dr.</b>  12       <b>Holford's mathematical analysis.</b>  13       Q. Well, are you aware of any evidence showing  14       that antibiotics are of limited value in warding off  15       or preventing deep joint infections?  16       MR. GORDON: Object to the form of the  17       question.  18       <b>A. I -- I have read, as you asked me earlier,</b>  19       <b>that biofilm can reduce the effectiveness of</b>  20       <b>antibiotics, if that was your question.</b>  21       Q. Right. And it -- it basically creates a  22       slime or a -- a -- a film over the infection and  23       antibiotics can't get at it; correct?  24       MR. GORDON: Same objection.  25       <b>A. I -- I'm not sure if that's how I would</b></p>	<p style="text-align: right;">Page 188</p> <p>1       <b>A. There was a series. One of them was the</b>  2       <b>differential capacity of the antibiotics to act upon</b>  3       <b>the bacteria that were most commonly associated with</b>  4       <b>the infections, a second I thought interesting was the</b>  5       <b>comment which I've quoted from Dr. Reed who said that</b>  6       <b>"Our infection rate doubled when we went to</b>  7       <b>Gentamicin," and I am sure that I -- there were others</b>  8       <b>at the moment I can't think of by name which have</b>  9       <b>shown the effectiveness of prophylactic antibiotics.</b>  10       <b>But in large part I would defer that, in terms of the</b>  11       <b>effectiveness, to Dr. Wenzel.</b>  12       Q. Well if you don't have an opinion on the  13       effectiveness, how can you opine that it's a  14       confounder?  15       <b>A. I have a statement from Dr. Reed from this</b>  16       <b>operating room who said that the infection rate went</b>  17       <b>up significantly when they used Gentamicin, and we</b>  18       <b>have evidence that the infectious rate -- infection</b>  19       <b>rate declined after the adoption of Teicoplanin.</b>  20       Q. I thought you just said you didn't do that  21       analysis.  22       <b>A. I -- I was looking at just the -- the -- the</b>  23       <b>crude numbers. I didn't do the analysis, I looked at</b>  24       <b>Dr. Holford's.</b>  25       Q. So you're relying on Dr. Reed for this</p>

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<p style="text-align: right;">Page 189</p> <p>1 statement that the infection rate doubled when we went 2 to Gentamicin; correct?</p> <p>3 <b>A. That was his statement, yes.</b></p> <p>4 Q. Okay. And -- and that was a statement that, 5 when you read that, you said, "Okay, I'm going to rely 6 on Dr. Reed for that." Right?</p> <p>7 <b>A. I thought that was an interesting statement.</b></p> <p>8 Q. And you said, "I'm going to rely on that;" 9 right?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. And then when Dr. Reed said things you 12 didn't agree with, you just set those aside; isn't 13 that right?</p> <p>14 <b>A. To some extent that's correct.</b></p> <p>15 Q. Okay. Cherry-picking, isn't that what it's 16 called?</p> <p>17 <b>A. No, no, no, no. I can explain how I got 18 there, so that's not cherry-picking.</b></p> <p>19 Q. Okay. Do you know whether Dr. Reed was 20 talking about deep joint infections versus superficial 21 wound infections?</p> <p>22 <b>A. Not without looking back at the document.</b></p> <p>23 Q. Okay. Do you know whether antibiotics are 24 better and perhaps more efficacious when it relates to 25 wound infections as opposed to deep joint infections?</p>	<p style="text-align: right;">Page 191</p> <p>1 references that you relied upon in connection with 2 your opinions; correct? For example, reference number 3 four on your list of documents relied upon.</p> <p>4 <b>A. Yes. I skipped it somehow. Thanks.</b></p> <p>5 Q. All right. So this is --</p> <p>6 This author of Exhibit 21 is the same doctor 7 as one of the other references that you relied upon in 8 connection with your expert opinions in this case; 9 correct?</p> <p>10 <b>A. Presumably. And this may even be the same 11 paper.</b></p> <p>12 Q. Okay.</p> <p>13 <b>A. How do you like that?</b></p> <p>14 Q. All right. So if we can take a look under 15 "Introduction," one, two, three -- four paragraphs 16 down, it says, "Many factors have been shown to reduce 17 the incidence of surgical wound infection, most of 18 which are now part of best practice. The value of 19 prophylactic antibiotics in clean-contaminated and 20 contaminated surgery is not contentious but the 21 benefits of prophylactic antibiotics in reducing wound 22 infection rates after clean surgery remain unclear. 23 Although it has been suggested that antibiotics are 24 beneficial this idea has not been supported by other 25 studies." Do you see that?</p>
<p style="text-align: right;">Page 190</p> <p>1 <b>A. I -- I don't know for sure.</b></p> <p>2 Q. That wasn't something you investigated when 3 you reached your conclusion that the change in 4 antibiotics was a confounder as it related to deep 5 joint infections during the McGovern period; correct?</p> <p>6 <b>A. I did not independently investigate that 7 question.</b></p> <p>8 Q. Do you believe that the -- that any changes 9 in wound dressing post surgery during the McGovern 10 period is a confounder?</p> <p>11 <b>A. I believe they changed dressings after the 12 end of the McGovern study.</b></p> <p>13 Q. Okay. 14 (Exhibit 21 was marked for 15 identification.)</p> <p>16 BY MS. CONLIN:</p> <p>17 Q. I've handed you what's been marked as 18 Deposition Exhibit 21, which is an article by Dr. 19 Melling et al, quote, "Effects of preoperative warming 20 on the incidence of wound infection after clean 21 surgery: a randomized controlled trial." Do you see 22 that?</p> <p>23 <b>A. I do.</b></p> <p>24 Q. And Dr. Melling was one of the individuals 25 that you relied -- or the author of one of the other</p>	<p style="text-align: right;">Page 192</p> <p>1 <b>A. I see that.</b></p> <p>2 Q. Okay. So this --</p> <p>3 I take it you had read this before you 4 rendered your opinions in this case; correct?</p> <p>5 <b>A. I'm sure I'd read this before I rendered my 6 opinions.</b></p> <p>7 Q. Okay. And one of the reasons you decided 8 that there wasn't evidence of an association between 9 the Bair Hugger and the increased risk of infection is 10 because there were studies on both sides; right? We 11 talked about that this morning.</p> <p>12 <b>A. I think that's right.</b></p> <p>13 Q. Okay. And this is an article that's saying 14 that there's sort of studies on both sides on whether 15 even administering any antibiotic -- or prophylactic 16 antibiotic after a clean surgery is unclear; correct?</p> <p>17 <b>A. That was the starting premise, yes.</b></p> <p>18 Q. Okay. But you've decided that the change in 19 antibiotics was a confounder in connection with 20 McGovern; correct?</p> <p>21 <b>A. Based on the McGovern data, yes.</b></p> <p>22 Q. You know the authors said that it wasn't a 23 confounder in their mind; correct?</p> <p>24 <b>A. I think they did in their depositions.</b></p> <p>25 Q. Okay.</p>

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<p>1 (Exhibit 22 was marked for 2 identification.) 3 BY MS. CONLIN: 4 Q. I've handed you, sir, what's been marked as 5 Deposition Exhibit 22, which is a study entitled 6 "Prophylactic antibiotics in elective hip and knee 7 arthroplasty," authored by Dr. Hickson among others. 8 Do you see that? 9 <b>A. I do.</b> 10 Q. You see that Dr. Reed is also an author on 11 this? 12 <b>A. I do.</b> 13 Q. Okay. If we can take a look at page 186 of 14 this. 15 <b>A. May I just look at the abstract first,</b> 16 <b>make --</b> 17 Q. Sure. 18 <b>A. Okay. Thank you.</b> 19 Q. Can you direct your attention to page 186 of 20 this, and direct your attention to the second 21 paragraph down starting with "Although..." It says, 22 "Although there is a large body of evidence for the 23 use of prophylactic antibiotics in primary hip and 24 knee arthroplasty, there is no clear benefit to using 25 one particular agent/regimen." Do you see that?</p>	<p>1 <b>A. I would have to look it up. And I think it</b> 2 <b>was muc -- mupirocin that was used, but I could look</b> 3 <b>at --</b> 4 <b>Probably it was in Gillson, but I'm not</b> 5 <b>sure.</b> 6 Q. Okay. In connection with -- 7 MS. CONLIN: Well I'll dig that out. Why 8 don't we just take a quick break here; we've been 9 going about an hour anyway. 10 THE REPORTER: Off the record, please. 11 (Recess taken.) 12 (Exhibit 23 was marked for 13 identification.) 14 BY MS. CONLIN: 15 Q. I've handed you, sir, what's been marked as 16 Deposition -- Borak Deposition Exhibit 23, which is 17 entitled "Implementing effective SSI surveillance" by 18 Julie Gillson and Gail Lowdon. 19 Is this what you were referencing before the 20 break in connection with your understanding that once 21 MSSA screening was undertaken in January of 2010, 22 there was decolonization with a topical antibiotic? 23 <b>A. This is the article I was referring to.</b> 24 Q. Okay. And then I'd just ask you to point 25 out for me where in the article the actual</p>
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<p>1 <b>A. I do.</b> 2 Q. Okay. Do you have any reason to dispute the 3 statements by Drs. Reed and Hickson as reported in 4 this -- 5 <b>A. I --</b> 6 Q. -- article? 7 <b>A. I don't.</b> 8 Q. Okay. So I'd like to direct your attention 9 to page 13 of your report regarding the MSSA 10 screening. 11 <b>A. Yes.</b> 12 Q. And I take it you also find that there is an 13 association between MSSA screening and an increased 14 risk of a prosthetic joint infection; correct? 15 <b>A. I believe that's correct, yes.</b> 16 Q. Okay. And you said that there was screening 17 implemented for MSSA, or methicillin sensitive 18 Streptococcus aureus, correct, in January of 2010? 19 <b>A. Yes, I did say that.</b> 20 Q. Okay. And is it -- and you also say that 21 there -- 22 Well, do you know if there was 23 decolonization after that? 24 <b>A. That's my understanding.</b> 25 Q. And what was the decolonization protocol?</p>	<p>1 decolonization procedure is outlined. I'll just 2 represent to you I -- I couldn't find it, so -- 3 MR. GORDON: I'll save you both time. It's 4 not in there. 5 <b>A. I -- I --</b> 6 <b>At the moment I don't see it. I'm not sure</b> 7 <b>if it's in the table, which I can't see.</b> 8 Q. I'll represent to you that I blew that up 9 and it doesn't say it there either, so I'm just 10 curious -- 11 MR. GORDON: I'll -- I'll stipulate to that. 12 MS. CONLIN: Okay. 13 Q. So where -- where did you get this notion 14 that the screening was followed by a decolonization 15 with a topical antibiotic mupir -- 16 <b>A. Mupirocin.</b> 17 Q. -- mupirocin? 18 <b>A. I think that I --</b> 19 <b>If I didn't find it in here and if I did not</b> 20 <b>see it in Dr. Reed's testimony, then I presume I</b> 21 <b>assumed that it would be the only purpose for doing</b> 22 <b>the MSSA screening; that is, to detect and then to</b> 23 <b>respond to it.</b> 24 Q. Well I guess my point is is how do you know 25 it was that particular topical antibiotic versus</p>

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<p style="text-align: right;">Page 197</p> <p>1 something else?</p> <p>2 <b>A. That is the one that has been used almost</b></p> <p>3 <b>universally, so I -- I am reasonably certain that I --</b></p> <p>4 <b>I would have expected that. And I thought I knew</b></p> <p>5 <b>that, but at the moment sitting here I can't point to</b></p> <p>6 <b>a place where I found that specific detail.</b></p> <p>7 Q. And you again, in connection with this MSSA</p> <p>8 screening, rely on statements by Dr. Reed; correct?</p> <p>9 <b>A. Well I pointed to Dr. Reed's statement.</b></p> <p>10 Q. Well you relied on it; correct?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. Okay.</p> <p>13 <b>A. Oh, okay. There. Okay. So it is Dr. Reed</b></p> <p>14 <b>who literally there said, "After MSSA screening, a</b></p> <p>15 <b>decolonization was introduced," and I took for granted</b></p> <p>16 <b>that that was referring to this time in this study of</b></p> <p>17 <b>concern that we have with McGovern.</b></p> <p>18 Q. Okay. Did you do any analysis as to whether</p> <p>19 MSSA infections went up after MSSA screening and</p> <p>20 decolonization was implemented in January 2010?</p> <p>21 <b>A. I understand from conversations -- I did not</b></p> <p>22 <b>look at the raw data -- that there were none reported</b></p> <p>23 <b>after the introduction of that process.</b></p> <p>24 Q. So you would disagree that there was an</p> <p>25 uptick in infections after MSSA screening was</p>	<p style="text-align: right;">Page 199</p> <p>1 MR. GORDON: Dotted green or blue?</p> <p>2 MS. CONLIN: Well whatever. It's the one</p> <p>3 dotted line with the circle.</p> <p>4 Q. Do you see that?</p> <p>5 <b>A. Yes.</b></p> <p>6 MS. CONLIN: Okay. And yeah, it does look</p> <p>7 blue, Mr. Gordon. Thank you. We'll refer to it as</p> <p>8 the dotted blue line.</p> <p>9 Q. You'll see that there's a reference point</p> <p>10 there of September 2008.</p> <p>11 Right here.</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. Okay. And then if you look, based on this</p> <p>14 graph, MSSA infections went down between September</p> <p>15 2008 and October 2009; correct?</p> <p>16 <b>A. It seems to be.</b></p> <p>17 Q. Okay. And then after October 2009 to</p> <p>18 November 2011, you'll see there's an uptick; correct?</p> <p>19 <b>A. I do see that.</b></p> <p>20 Q. Okay. Is that something that you</p> <p>21 investigated in connection with your view that the</p> <p>22 MSSA screening renders the McGov -- is a confounder to</p> <p>23 the McGovern report?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>
<p style="text-align: right;">Page 198</p> <p>1 implemented?</p> <p>2 <b>A. I thought that there were no MSSA</b></p> <p>3 <b>infections.</b></p> <p>4 <b>(Exhibit 24 was marked for</b></p> <p>5 <b>identification.)</b></p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you, sir, what's been marked as</p> <p>8 Borak Deposition Exhibit 24, which is a document</p> <p>9 entitled "Surveillance of surgical site infections in</p> <p>10 NHS hospitals in England." Do you see that?</p> <p>11 <b>A. I do.</b></p> <p>12 Q. Okay. And is this something you've seen</p> <p>13 before?</p> <p>14 <b>A. I have seen documents that look like this.</b></p> <p>15 <b>I don't know if this is the one I saw.</b></p> <p>16 Q. Okay. If we can direct your attention to</p> <p>17 page 30, --</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. -- Figure 11, "Trends in micro-organisms</p> <p>20 reported as causing inpatient SSIs, proportions with</p> <p>21 lower and upper 95 percent confidence, all surgical</p> <p>22 categories, NHS hospitals, England." Do you see that?</p> <p>23 <b>A. I do.</b></p> <p>24 Q. Okay. Now you'll see the dotted green line</p> <p>25 is MSSA infections; correct?</p>	<p style="text-align: right;">Page 200</p> <p>1 <b>A. I would not have looked at this since this</b></p> <p>2 <b>is a composite of all of the hospitals in England -- I</b></p> <p>3 <b>think it is all of them -- and it is all forms of</b></p> <p>4 <b>surgery, and so I'm not quite sure what one could have</b></p> <p>5 <b>drawn from this or what it would have told me other</b></p> <p>6 <b>than the fact that there was heterogeneity in the</b></p> <p>7 <b>operating room procedures in the NHS hospitals.</b></p> <p>8 Q. Do you know which hospitals were included in</p> <p>9 this?</p> <p>10 <b>A. I'm happy to look at the beginning.</b></p> <p>11 Q. Well you just said it includes all the</p> <p>12 hospitals. I'm wondering if you know that or you're</p> <p>13 just assuming that.</p> <p>14 <b>A. I am assuming it based upon what I saw in a</b></p> <p>15 <b>quick look at the document, but I'm happy to look</b></p> <p>16 <b>further. "Since July 2008 hospitals were required" --</b></p> <p>17 <b>I mean I'm happy to take time to look for</b></p> <p>18 <b>the number, but --</b></p> <p>19 Q. No. I -- I was just curious, when you said</p> <p>20 that it included more hospitals than the three at</p> <p>21 issue in McGovern, whether you knew that or you were</p> <p>22 just speculating.</p> <p>23 <b>A. Oh, no, no, no, I'm not speculating, but I</b></p> <p>24 <b>don't know what the number is.</b></p> <p>25 Q. Okay.</p>

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<p>1       <b>A. This is a composite of the NHS system. We</b>  2       <b>are looking at, in McGovern, one hospital.</b>  3       Q. Okay. But you --  4       Your view is that because the MSSA data on  5       that chart we just looked at isn't specific to deep  6       joint infections, it wouldn't be a fair comparison; is  7       that right?  8       <b>A. No. It wouldn't be a fair comparison</b>  9       <b>because it's looking at, I believe, most if not all of</b>  10       <b>the NHS hospitals in England. I don't know about</b>  11       <b>their implementation of procedures and protocols. I</b>  12       <b>believe I saw something here about a lack of</b>  13       <b>consistency in the applications of protocols. I think</b>  14       <b>there are a variety of other considerations. So I</b>  15       <b>wouldn't use this to inform my thinking about</b>  16       <b>Northumbria.</b>  17       Q. And one of the reasons that you just stated  18       that you didn't think it would be a fair comparison is  19       because it's including other surgeries, not just deep  20       joint infections; correct?  21       <b>A. Yes.</b>  22       Q. Other types of infections.  23       <b>A. Yes.</b>  24       Q. And you don't think it would be fair to  25       extrapolate from one type of infection in one part of</p>	<p>1       <b>(Exhibit 25 was marked for</b>  2       <b>identification.)</b>  3       BY MS. CONLIN:  4       Q. I've handed you, sir, what's been marked as  5       Borak Exhibit 25, which I think is your reference --  6       <b>A. I think it's number 30.</b>  7       Q. -- your reference number 30; correct?  8       <b>A. I believe that's correct.</b>  9       Q. Thank you. Okay. And this was one of the  10       things that you relied on to suggest that  11       decolonization with a topical antibiotic, mupirocin,  12       has been shown to significantly reduce risk of post-  13       surgical infections, including hip and knee  14       replacements; correct?  15       <b>A. Yes.</b>  16       Q. Okay. I'd like to direct your attention to  17       the third paragraph of this article.  18       <b>A. After the introduction or in the abstract?</b>  19       Q. Internal page 2385. Got a chart at the top.  20       <b>A. Third page. I thought you said paragraph.</b>  21       <b>Okay.</b>  22       Q. In the paragraph about "Of the 19  23       studies..."  24       <b>A. "Of the 19 studies..." Yes.</b>  25       Q. On the right-hand side, midway down, it</p>
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<p>1       the body to a deep joint infection even if it's MSSA;  2       correct?  3       <b>A. I -- I -- I --</b>  4       <b>Yes. I think this would raise the question</b>  5       <b>whether this added or altered my thinking, and I</b>  6       <b>referred ultimately to a comment which came literally</b>  7       <b>from Dr. Reed who said that "In the fight against</b>  8       <b>PJI" -- prosthetic joint infections -- "after MSSA</b>  9       <b>screening and decolonization was introduced, one NHS</b>  10       <b>joint replacement unit, the MSSA infection was reduced</b>  11       <b>from .84 to .26." I believe that is speaking about</b>  12       <b>Wansbeck, though in looking at the document I couldn't</b>  13       <b>tell which of the three hospitals it was, but I</b>  14       <b>presume it is because it's where there was the data.</b>  15       MS. CONLIN: Move to strike as non-  16       responsive.  17       Can you read my question back?  18       (Record read by the court reporter.)  19       <b>A. I -- I have difficulty extrapolating from</b>  20       <b>this document. I might also have --</b>  21       Q. I didn't ask you that. I asked you a  22       straight-up question.  23       MS. CONLIN: Could you read it back again.  24       (Record read by the court reporter.)  25       <b>A. It might not be fair.</b></p>	<p>1       says, "The majority of studies detected S. aureus  2       colonization using cultures, most SSIs were defined by  3       CDC criteria, the majority of studies did not  4       differentiate between superfer -- superficial versus  5       deep infections, and most of the patients who  6       underwent decolonization were positive for S. aureus  7       on nasal screens." Do you see that?  8       <b>A. I do.</b>  9       Q. In connection with your discussion of MSSA  10       screening, you bundled infections regardless of  11       whether they were deep joint infections; correct?  12       MR. GORDON: Object to the form of the  13       question.  14       <b>A. I cited a paper which I think may have</b>  15       <b>bundled it.</b>  16       Q. In -- in support of your belief that the  17       implementation of MSSA screening and decolonization is  18       a confounding factor in McGovern; correct?  19       <b>A. Yes. Correct.</b>  20       <b>(Exhibit 26 was marked for</b>  21       <b>identification.)</b>  22       THE WITNESS: Thank you.  23       BY MS. CONLIN:  24       Q. I've handed you what's been marked as Borak  25       Exhibit 26, which is a JAMA survey entitled "Centers</p>

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<p style="text-align: right;">Page 205</p> <p>1 for Disease Control and Preven -- Prevention Guideline</p> <p>2 for the Prevention of Surgical Site Infection, 2017;"</p> <p>3 correct?</p> <p>4 <b>A. Correct.</b></p> <p>5 Q. And this was something that you relied on in</p> <p>6 connection with your opinions in this case; correct?</p> <p>7 <b>A. Correct.</b></p> <p>8 Q. Okay. I'd like to direct --</p> <p>9 Now by the way, you understand that this</p> <p>10 particular recommendation didn't advocate one type of</p> <p>11 patient warming over another; correct?</p> <p>12 <b>A. I don't remember that.</b></p> <p>13 Q. Okay. That they said keep patients warm,</p> <p>14 but they didn't advocate a specific --</p> <p>15 <b>A. Okay. That is probably correct. I don't</b></p> <p>16 <b>specifically remember.</b></p> <p>17 Q. And you're not suggesting that there's</p> <p>18 something special about the Bair Hugger that keeps a</p> <p>19 patient warmer; correct?</p> <p>20 <b>A. I understood that the Bair Hugger warmed</b></p> <p>21 <b>more quickly, but I can't tell you where I know that</b></p> <p>22 <b>from.</b></p> <p>23 Q. Okay. Now if we can take a look at E4,</p> <p>24 under "Normothermia," do you see that --</p> <p>25 <b>A. Yes.</b></p>	<p style="text-align: right;">Page 207</p> <p>1 basically a low-molecular-weight heparin similar to</p> <p>2 trinzaparin, compared to Xarelto, which --</p> <p>3 <b>A. I know that it --</b></p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question.</p> <p>6 <b>A. They -- they reviewed a number of studies,</b></p> <p>7 <b>none of which compared trinzaparin.</b></p> <p>8 Q. So you were aware of that.</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. And your point is is you can't rely on that</p> <p>11 because enoxaparin is -- even though it's another type</p> <p>12 of low-molecular-weight heparin, it's not the same as</p> <p>13 trinzaparin; correct?</p> <p>14 <b>A. Well that was one, and the second is that</b></p> <p>15 <b>the papers they reference don't actually define</b></p> <p>16 <b>surgical infection.</b></p> <p>17 Q. So with respect --</p> <p>18 Well fair point. You'd agree with me that</p> <p>19 you got to know whether it's a deep joint infection or</p> <p>20 some other type of infection.</p> <p>21 <b>A. I -- I -- I didn't -- I didn't know what</b></p> <p>22 <b>they were looking at. I tried. It was cited only --</b></p> <p>23 <b>In each of the four papers they reference</b></p> <p>24 <b>there, it is only cited in a table with a footnote,</b></p> <p>25 <b>and the footnote doesn't lead -- is a -- is a -- is a</b></p>
<p style="text-align: right;">Page 206</p> <p>1 Q. -- in the left-hand side underneath</p> <p>2 "Glycemic Control?"</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. At the end of it it says, "...Other</p> <p>5 Guidelines section of the narrative summary for this</p> <p>6 question (eAppendix 1 one of the Supplement)." Do you</p> <p>7 see that?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. Okay. Did you look at that supplement to --</p> <p>10 <b>A. I believe I did.</b></p> <p>11 Q. Okay. So you're aware that in that</p> <p>12 supplement the CDC found no benefit to using CHG-</p> <p>13 alcohol compared to iodophor alcohol; correct?</p> <p>14 <b>A. I actually don't recall that.</b></p> <p>15 Q. Okay. Are you aware that the CDC found no</p> <p>16 benefit to CHG versus povidone-iodine?</p> <p>17 <b>A. I don't recall that.</b></p> <p>18 Q. Okay. Would that be something that would be</p> <p>19 important in connection with your view that the change</p> <p>20 in skin preparation is a confounder that undercuts the</p> <p>21 validity of McGovern?</p> <p>22 <b>A. I would probably go back and look at it</b></p> <p>23 <b>again, and I may do so tonight.</b></p> <p>24 Q. Okay. Are you aware that that appendix</p> <p>25 found no benefit to using enoxaparin, which is a --</p>	<p style="text-align: right;">Page 208</p> <p>1 <b>blind path.</b></p> <p>2 Q. Okay. And you set aside the</p> <p>3 thromboprophylaxis discussion because you didn't see a</p> <p>4 comparison between -- between trinzaparin and Xarelto</p> <p>5 directly; correct?</p> <p>6 <b>A. I did not see such a comparison.</b></p> <p>7 Q. And you felt like it would be inappropriate</p> <p>8 to use the reference to enoxaparin even though it's</p> <p>9 similar to trinzaparin because it's different; is that</p> <p>10 right?</p> <p>11 <b>A. It's different.</b></p> <p>12 Q. And that's one of the reasons you set it</p> <p>13 aside; correct?</p> <p>14 <b>A. Correct.</b></p> <p>15 Q. Now I'd like to direct your attention to</p> <p>16 page nine of your expert report, Borak Exhibit 1, "The</p> <p>17 McGovern Study: Background." Are you there?</p> <p>18 <b>A. I am.</b></p> <p>19 Q. Okay. And in paragraph 22 you say, "The</p> <p>20 report -- report by McGovern is the only published</p> <p>21 study that purports to show an increased risk of SSI</p> <p>22 associated with the use of the Bair Hugger."</p> <p>23 <b>A. I did say that.</b></p> <p>24 Q. Okay. And there --</p> <p>25 Since that time there's been the Augustine</p>

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<p style="text-align: right;">Page 209</p> <p>1 paper that's been published; correct?</p> <p>2 <b>A. Correct.</b></p> <p>3 Q. And I take it that doesn't change your</p> <p>4 views.</p> <p>5 <b>A. No. I think little of the Augustine paper.</b></p> <p>6 Q. You think little of the Aug --</p> <p>7 Why is that?</p> <p>8 <b>A. It doesn't seem to follow its protocol. It</b></p> <p>9 <b>seems to have cherry-picked data.</b></p> <p>10 Q. What kind of cherry-picking?</p> <p>11 <b>A. Hmm. There are data from Ridgeview Medical</b></p> <p>12 <b>Center, that were apparently provided under whatever</b></p> <p>13 <b>process legally, which shows a compilation of knee and</b></p> <p>14 <b>hip surgeries and infectious rates for four years,</b></p> <p>15 <b>2006, 2007, 2008, 2009. Looking at the recent</b></p> <p>16 <b>Augustine paper, it appears that he only dealt with</b></p> <p>17 <b>the knees, not the hips nor the two combined, that he</b></p> <p>18 <b>compared 2006 knees to 2008 and 2009 knees, which was</b></p> <p>19 <b>not at all what he said would be the protocol, which</b></p> <p>20 <b>was a two-month or three-month washout period, and</b></p> <p>21 <b>that he selectively -- selectively excluded the 2007</b></p> <p>22 <b>data. And so it doesn't look to me as though the</b></p> <p>23 <b>Augustine paper is based upon legitimate data, it</b></p> <p>24 <b>looks as though -- well "legitimate" -- real but</b></p> <p>25 <b>selected in a way to influence the appearance of an</b></p>	<p style="text-align: right;">Page 211</p> <p>1 sure.</p> <p>2 <b>A. For the moment. It's possible something</b></p> <p>3 <b>else will occur to me, but I haven't pulled out my</b></p> <p>4 <b>notes.</b></p> <p>5 Q. Okay. If the McGovern study is valid, would</p> <p>6 you agree with me that there is a substantial increase</p> <p>7 in the risk of infection through use of the Bair</p> <p>8 Hugger?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question.</p> <p>11 <b>A. Hypothetically, if there were no problems</b></p> <p>12 <b>with the McGovern paper, then its conclusions could be</b></p> <p>13 <b>relied upon.</b></p> <p>14 Q. Okay. And it would show a substantial</p> <p>15 increased risk of a deep joint infection --</p> <p>16 <b>A. Hypothetically, if it were different --</b></p> <p>17 Q. -- through use of Bair Hugger.</p> <p>18 <b>A. Hypothetically, if there were no problems</b></p> <p>19 <b>with the McGovern paper and if the results as</b></p> <p>20 <b>presented were correct, then it would show a 3.8-fold</b></p> <p>21 <b>increased risk with the Bair Hugger that was</b></p> <p>22 <b>statistically significant.</b></p> <p>23 Q. Okay. And if --</p> <p>24 One of the things that Professor Holford did</p> <p>25 is say, well, there -- Dr. Reed testified he thought</p>
<p style="text-align: right;">Page 210</p> <p>1 <b>outcome.</b></p> <p>2 Q. How about the other two centers?</p> <p>3 <b>A. I don't have any data on them.</b></p> <p>4 Q. Now in paragraph 24 --</p> <p>5 Oh, by the way, is there anything else that</p> <p>6 you want to say about why you think very little of the</p> <p>7 Augustine paper?</p> <p>8 <b>A. Well it's clear that he doesn't provide</b></p> <p>9 <b>enough information about the cases, and his statement,</b></p> <p>10 <b>which is that nothing else changed, is contradicted by</b></p> <p>11 <b>statements from that Ridgeview Medical Center itself,</b></p> <p>12 <b>so my sense of it is that the data are not what he</b></p> <p>13 <b>presents or that he misrepresents the data, and that</b></p> <p>14 <b>he excluded a year's worth of data which would not</b></p> <p>15 <b>have enhanced the comparison, that he deviated from</b></p> <p>16 <b>the protocol, and that he excluded the hip data.</b></p> <p>17 Q. Excluded the what? I'm sorry.</p> <p>18 <b>A. Excluded the hip data --</b></p> <p>19 Q. Oh "hip." Okay. Yeah.</p> <p>20 <b>A. -- and did not present the paper properly.</b></p> <p>21 <b>He says that he did a replica or something -- I'm</b></p> <p>22 <b>paraphrasing -- of the McGovern study, but of course</b></p> <p>23 <b>he clearly did not.</b></p> <p>24 Q. If the --</p> <p>25 Is that everything? I'm just trying to make</p>	<p style="text-align: right;">Page 212</p> <p>1 there was one more infection in each group, then</p> <p>2 running those numbers is a 2.76 increased risk of</p> <p>3 infection. Would you consider that substantial?</p> <p>4 MR. GORDON: It's actually 2.86.</p> <p>5 MS. CONLIN: 2.86. Thank you for that</p> <p>6 correction.</p> <p>7 <b>A. The word "substantial" is awfully</b></p> <p>8 <b>subjective. I don't -- I don't think I used it, but</b></p> <p>9 <b>maybe I would. I would not use it necessarily for</b></p> <p>10 <b>2.76.</b></p> <p>11 Q. But for 3.8, you would call that a</p> <p>12 significantly increased odds ratio.</p> <p>13 <b>A. I -- I think it was significantly increased.</b></p> <p>14 <b>I think that's what the arithmetics showed.</b></p> <p>15 Q. Well you used the term "significantly</p> <p>16 increased odds ratio" --</p> <p>17 <b>A. Yes.</b></p> <p>18 Q. -- for SSI during the Bair Hugger period --</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. -- if the McGovern data is accurate;</p> <p>21 correct?</p> <p>22 <b>A. Yes.</b></p> <p>23 Q. Okay. Now in paragraph 24 you say, "The</p> <p>24 McGovern authors noted that 'unfortunately' during the</p> <p>25 study period there was a change in the prophylactic</p>

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<p>1 antibiotic regimen and two changes in their</p> <p>2 thromboprophylaxis regimen." Do you see that?</p> <p>3 <b>A. I do.</b></p> <p>4 Q. Where does that quote "unfortunately" come</p> <p>5 from?</p> <p>6 <b>A. I'd have to look and see whether it's in</b></p> <p>7 <b>McGovern or in some of the depositions.</b></p> <p>8 Q. Okay. So you weren't suggesting an</p> <p>9 attribution to the article itself.</p> <p>10 <b>A. I don't know. I can look and see. I don't</b></p> <p>11 <b>remember.</b></p> <p>12 Q. Okay. And you write in 25 that "The authors</p> <p>13 concluded that their study did not establish a causal</p> <p>14 basis for an association between Bair Hugger and risk</p> <p>15 of SSI..." correct?</p> <p>16 <b>A. Yes, that's correct.</b></p> <p>17 Q. Okay. Now you read the depositions of at</p> <p>18 least some of the authors; correct?</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. Okay. And you understand that they hadn't</p> <p>21 done a full epidemiological study at the time the</p> <p>22 McGovern paper was published; correct?</p> <p>23 <b>A. I'm not sure what you mean by "a full</b></p> <p>24 <b>epidemiological study," but perhaps you can refer to</b></p> <p>25 <b>the statement that you're referring to.</b></p>	<p>1 correct, by both Drs. Reed and McGovern?</p> <p>2 <b>A. I certainly quoted from them, yes.</b></p> <p>3 <b>(Discussion off the stenographic record.)</b></p> <p>4 <b>(Exhibit 27 was marked for</b></p> <p>5 <b>identification.)</b></p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you a portion of Dr. McGovern's</p> <p>8 deposition.</p> <p>9 By the way, did you get both days of Dr.</p> <p>10 McGovern's deposition?</p> <p>11 <b>A. Yes, I did.</b></p> <p>12 Q. Okay.</p> <p>13 <b>A. But forgive me, I thought you were asking me</b></p> <p>14 <b>a question a moment ago about Dr. Reed.</b></p> <p>15 Q. No, I asked you about one of the authors.</p> <p>16 <b>A. Oh. And I thought you said it was Dr. Reed.</b></p> <p>17 <b>Maybe I'm wrong. Maybe I misheard.</b></p> <p>18 Q. And if you take a look at the bottom of page</p> <p>19 114 where Mr. Gordon was questioning him:</p> <p>20 "Question: Based on the evidence, you</p> <p>21 believe it would have been reasonable to imply there</p> <p>22 was a causation?"</p> <p>23 Mr. Gordon, quote -- or --</p> <p>24 "Question: Based on the evidence, you</p> <p>25 believe it would have been reasonable for your paper</p>
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<p>1 Q. Well you understand that they hadn't gone</p> <p>2 out and done a bunch of research beyond what -- the</p> <p>3 McGovern paper itself. I mean they -- they -- they</p> <p>4 were reporting on work they did; correct?</p> <p>5 <b>A. They were reporting the data that they said</b></p> <p>6 <b>they had collected at this hospital.</b></p> <p>7 Q. Okay. And, for example, they don't</p> <p>8 reference the Stocks paper or the Darouiche paper;</p> <p>9 correct?</p> <p>10 <b>A. They did not refer to that, but I --</b></p> <p>11 <b>Yes, I don't think they did.</b></p> <p>12 Q. Okay. And you're aware that at least one of</p> <p>13 the authors testified under oath, under penalty of</p> <p>14 perjury, that a causal connection if properly</p> <p>15 qualified could be made; correct?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, mischaracterizes the testimony.</p> <p>18 <b>A. I -- I don't recall that. Which expert was</b></p> <p>19 <b>that -- or which author?</b></p> <p>20 Q. I think it was Dr. Reed. I can dig it out.</p> <p>21 Do you recall reading that?</p> <p>22 <b>A. I don't specifically. I've cited something</b></p> <p>23 <b>else from Dr. Reed's deposition.</b></p> <p>24 Q. Because you did cite throughout your report</p> <p>25 where helpful your position statements that were made,</p>	<p>1 to imply a causal connection?</p> <p>2 "Answer: If properly qualified, yes."</p> <p>3 Do you see that?</p> <p>4 <b>A. I'm sorry, direct me to which page.</b></p> <p>5 Q. Page one -- internal page 115. Bottom of</p> <p>6 114, top of 115. Do you see that?</p> <p>7 <b>A. I'm looking at the next interaction, which</b></p> <p>8 <b>is "What would the proper qualifications be?"</b></p> <p>9 <b>I see what you've read.</b></p> <p>10 Q. Okay. And it's your opinion that not only</p> <p>11 can you not draw a causal connection based on a review</p> <p>12 of all the evidence, but you can't even suggest an</p> <p>13 association between the Bair Hugger and an increased</p> <p>14 risk of infection; isn't that right?</p> <p>15 <b>A. No. There's clearly an association that's</b></p> <p>16 <b>been made by the McGovern paper. What I've said is I</b></p> <p>17 <b>find no evidence to indicate that there is a</b></p> <p>18 <b>causation.</b></p> <p>19 Q. Well let's take a look. I thought we went</p> <p>20 over this this morning. It took us a while to</p> <p>21 establish it.</p> <p>22 You write in paragraph 74c, "The McGovern</p> <p>23 report relied on truncated and incorrect --</p> <p>24 incorrectly tabulated data. When those irregularities</p> <p>25 are corrected, the study data do not pry -- provide</p>

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<p style="text-align: right;">Page 217</p> <p>1 evidence that the Bair Hugger is associated with a 2 significant increase in SSI;" correct? 3 <b>A. The operative word there is "a significant 4 increase," and once those data errors are corrected, 5 the association becomes non-significant.</b> 6 Q. Well you know that the study authors, in 7 addition to saying they checked the numbers three 8 times before they went in the final report, Dr. Reed, 9 for example, said that if you added one infection on 10 each side, it would change the odds ratio very -- very 11 slightly; right? 12 <b>A. I -- I saw such a statement.</b> 13 Q. Okay. And you -- you disagree with that, 14 too; don't you? 15 <b>A. I relied upon Dr. Holford's calculations 16 based on that, --</b> 17 Q. Okay. 18 <b>A. -- both in his paper and in -- in his report 19 and in footnote one of his report.</b> 20 Q. But you would disagree with Dr. Reed that it 21 would change the odds ratio very slightly; correct? 22 <b>A. I don't know what he meant by "very 23 slightly." But yes, I don't agree that it would have 24 retained significance.</b> 25 Q. Even if it had at p-value of under .05?</p>	<p style="text-align: right;">Page 219</p> <p>1 And what is your view of the importance of 2 establishing a p-value in connection with an 3 epidemiological undertaking? 4 <b>A. I think it is a useful guiding datum. It 5 gives you some sense of what is going on, but it also 6 has a certain quality of subjectiveness.</b> 7 Q. Okay. So if something falls just below or 8 just above the known p-value of .05, that's not the 9 end of the inquiry is your -- is your view. 10 <b>A. I believe that that is not the end of one's 11 inquiry.</b> 12 Q. Okay. So something can have a causal 13 connection even though the p-value is less than .05; 14 correct? 15 <b>A. You mean more than.</b> 16 Q. I'm sorry, more than .05. 17 <b>A. Yes. And something can be a confounder even 18 when its association on a univariate level is greater 19 than p equals .05.</b> 20 Q. Okay. What if it's one? 21 <b>A. What if it's p equals one?</b> 22 Q. Uh-huh. Can it be a confounder? 23 <b>A. I don't have an answer to that question. 24 Probably not, but I don't know.</b> 25 Q. Okay. You don't have an opinion on that one</p>
<p style="text-align: right;">Page 218</p> <p>1 <b>A. I would have to see that.</b> 2 Q. Okay. Do you think if -- 3 Well, let me ask you this: Do you -- do 4 you -- 5 You don't have an opinion on whether 6 chi-squared or Fisher's exact is the appropriate 7 methodology for deriving a p-value; correct? 8 <b>A. Well I could tell you what --</b> 9 Q. In the McGovern study. And I'm just asking 10 you about your report, I'm not interested in your 11 thoughts on it. 12 In your report you don't opine on the 13 appropriateness -- 14 <b>A. I do not o --</b> 15 Q. -- of using chi-squared -- 16 <b>A. I have not opined upon exact test versus 17 chi-square.</b> 18 Q. Okay. And you express no opinion on the 19 appropriateness of the use of chi-squared in 20 connection with McGovern. 21 <b>A. I did not opine in my report.</b> 22 Q. You got to wait until I'm finished -- 23 <b>A. I'm sorry.</b> 24 Q. -- so we're not talking over each other. 25 Okay.</p>	<p style="text-align: right;">Page 220</p> <p>1 way or another. 2 <b>A. Not on a univariate.</b> 3 Q. And you didn't take that into account in 4 conjunction with your opinions on what is a confounder 5 in connection with McGovern and what's not; correct? 6 <b>A. I didn't take what into account?</b> 7 Q. Whether any of these changes, if you added 8 them up, had a p-value of one. 9 <b>A. That's not what we're talking about. 10 It's --</b> 11 <b>I'm sorry, forgive me. Your statement is a 12 misstatement. Perhaps you should ask your question 13 again.</b> 14 Q. Okay. You didn't, in connection with 15 deciding whether something was a confounder, take into 16 account the strength of association or the p-value; 17 correct? 18 <b>A. Did I?</b> 19 Q. Yes. 20 <b>A. I was not looking at p-values. I think I 21 was not looking at p-values. I was largely looking at 22 the evidence indicating that there were associations.</b> 23 Q. Right. You were using -- 24 You were reading stuff and using your 25 scientific judgment; correct?</p>

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<p style="text-align: right;">Page 221</p> <p>1 <b>A. And my knowledge, yes.</b></p> <p>2 Q. Okay. Because, as we talked about earlier</p> <p>3 in the day, there's an element of epidemiology that</p> <p>4 involves scientific judgment; correct?</p> <p>5 <b>A. I think scientific judgment is an important</b></p> <p>6 <b>thing, yes.</b></p> <p>7 Q. Okay. And that's what you did here in</p> <p>8 conjunction with deciding what you thought was a</p> <p>9 confounder and what you thought wasn't a confounder;</p> <p>10 correct?</p> <p>11 <b>A. It was part of what I did.</b></p> <p>12 Q. I'd like to direct your attention to page 11</p> <p>13 of your report starting under the heading "The</p> <p>14 McGovern Study: Sources of Confounding and Systematic</p> <p>15 Bias."</p> <p>16 <b>A. Correct.</b></p> <p>17 Q. Okay. And in paragraph 27 you talk about</p> <p>18 Gillson and Lowdon, that "...the Northumbria</p> <p>19 Healthcare Trust was regularly informed by the Health</p> <p>20 Protection Agency during 2008 and 2009 that it was 'a</p> <p>21 high outlier for SSI.'" Do you see that?</p> <p>22 <b>A. I do.</b></p> <p>23 Q. Do you know whether it was a high outlier</p> <p>24 for deep joint infections?</p> <p>25 <b>A. I understood that to be what they were</b></p>	<p style="text-align: right;">Page 223</p> <p>1 <b>A. I didn't have any evidence of that.</b></p> <p>2 Q. Okay. Did you do any investigation as to</p> <p>3 whether there was underreporting going on by other</p> <p>4 hospitals in the U.K.?</p> <p>5 <b>A. I only know that -- that this hospital was</b></p> <p>6 <b>reporting much higher than the national rates. I've</b></p> <p>7 <b>looked at some data on that.</b></p> <p>8 Q. Okay. Did you do an investigation --</p> <p>9 Can you answer my question? Did you do an</p> <p>10 investigation as to whether Dr. Reed was correct in</p> <p>11 his statement that there was underreporting going on</p> <p>12 at other hospitals during this time period?</p> <p>13 <b>A. I did no such investigation.</b></p> <p>14 Q. You also -- I take it paragraph 28 is --</p> <p>15 You're relying on Dr. Holford for the</p> <p>16 statements and conclusions in paragraph 28 in your</p> <p>17 report?</p> <p>18 <b>A. Yes, that's correct.</b></p> <p>19 Q. Okay. And if he's wrong, you're wrong;</p> <p>20 right?</p> <p>21 <b>A. If he's wrong, I'd have to revisit it. Yes.</b></p> <p>22 Q. Okay. And then in paragraph 29 you say,</p> <p>23 "The analysis by Dr. Holford raises another concern,</p> <p>24 the possibility that the data included in the McGovern</p> <p>25 study had been 'cherry-picked.'" Do you see that?</p>
<p style="text-align: right;">Page 222</p> <p>1 <b>talking about.</b></p> <p>2 Q. Based on what?</p> <p>3 <b>A. The focus of the Gillson and Lowdon paper.</b></p> <p>4 <b>But maybe I overstate it. I'm happy to look again.</b></p> <p>5 <b>It's clearly within the orthopedic</b></p> <p>6 <b>department. I don't know whether they specifically</b></p> <p>7 <b>note -- they say that there was a certain criteria</b></p> <p>8 <b>which included --</b></p> <p>9 <b>Well my initial read here does not</b></p> <p>10 <b>specifically differentiate the types of infections.</b></p> <p>11 Q. Okay. You don't know whether the</p> <p>12 Northumbria Healthcare Trust was a high outlier for</p> <p>13 deep joint infections; do you, sir?</p> <p>14 <b>A. No, not specifically. I guess I do not.</b></p> <p>15 Q. Okay. And you say, "This was confirmed by</p> <p>16 Dr. Reed in his deposition." So you relied on Dr.</p> <p>17 Reed for support for that statement about Northumbria</p> <p>18 being a high outlier for SSI; correct?</p> <p>19 <b>A. I guess I did, yes.</b></p> <p>20 Q. Okay. You also know that Dr. Reed testified</p> <p>21 that he felt that other hospitals in the trust were</p> <p>22 underreporting.</p> <p>23 <b>A. I read that.</b></p> <p>24 Q. Okay. But you didn't rely on that; did you,</p> <p>25 sir?</p>	<p style="text-align: right;">Page 224</p> <p>1 <b>A. I did.</b></p> <p>2 Q. And you say, "As noted above, appropriate</p> <p>3 SSI data were available for 9 months from October '07</p> <p>4 to June '08, but they were excluded from the McGovern</p> <p>5 report." Do you see that?</p> <p>6 <b>A. Yes.</b></p> <p>7 Q. Okay. You're aware that it wasn't until</p> <p>8 July of 2008 that there was a robust surveillance and</p> <p>9 reporting of infections at Wansbeck; correct?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question.</p> <p>12 <b>A. I -- I have seen conflicting information</b></p> <p>13 <b>about when --</b></p> <p>14 <b>I've seen information from Dr. Reed's</b></p> <p>15 <b>depositions and I've seen stuff from the Gillson</b></p> <p>16 <b>paper, and I don't know what date it started. I think</b></p> <p>17 <b>I understand that much of the data that comprise the</b></p> <p>18 <b>McGovern 16/Albrecht 10 were compiled -- some of it</b></p> <p>19 <b>was compiled ongoing and some of it was retrospective,</b></p> <p>20 <b>and I don't know which was which, so I don't know when</b></p> <p>21 <b>the evaluations really began.</b></p> <p>22 Q. Okay. Without having evidence to know</p> <p>23 whether Dr. Reed was correct that there wasn't</p> <p>24 complete data reporting until July 2008, you still</p> <p>25 felt comfortable opining in this case that there was</p>

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<p>1 cherry-picking and manipulation with respect to the</p> <p>2 start date; correct, sir?</p> <p>3 MR. GORDON: Object to the form of --</p> <p>4 <b>A. I -- I didn't say --</b></p> <p>5 MR. GORDON: -- the question.</p> <p>6 <b>A. -- that there was cherry-picking, I said</b></p> <p>7 <b>that the possibility is there based upon the fact that</b></p> <p>8 <b>there were these data for nine months. And I believe</b></p> <p>9 <b>I have seen from some deposition exhibits</b></p> <p>10 <b>prepublication figures, graphs, which suggest a number</b></p> <p>11 <b>of different start dates for this series of cases, one</b></p> <p>12 <b>which began in September rather than in July, which</b></p> <p>13 <b>makes me think that the start date was subject to some</b></p> <p>14 <b>manipulation or option.</b></p> <p>15 Q. Well those were start dates with respect to</p> <p>16 the SS -- SSI bundle. I'm talking about robust</p> <p>17 reporting with respect to deep joint infections in</p> <p>18 knees and hips. You have no -- you have no evidence</p> <p>19 to suggest that Dr. Reed was lying when he said that</p> <p>20 the reason they started in July of '08 was because</p> <p>21 that was when they felt there was full and robust</p> <p>22 reporting available.</p> <p>23 MR. GORDON: Object to the --</p> <p>24 Q. Is that right?</p> <p>25 MR. GORDON: Object to the form of the</p>	<p>1 <b>September, and so I think that there was some ability</b></p> <p>2 <b>to alter the starting date. That's the first piece.</b></p> <p>3 <b>The second piece, it may be entirely coincidental, but</b></p> <p>4 <b>I think that the Holford analysis of statistical</b></p> <p>5 <b>significant starting dates is very interesting because</b></p> <p>6 <b>had it started September instead of July, then the</b></p> <p>7 <b>effect of switching from Bair Hugger to Hot Dog would</b></p> <p>8 <b>not have been statistically significant; July was</b></p> <p>9 <b>statistically significant; June and August were not.</b></p> <p>10 <b>It's --</b></p> <p>11 <b>It may be just coincidence, I don't know,</b></p> <p>12 <b>that's why I say it raises the possibility.</b></p> <p>13 Q. Well don't you think you need some evidence</p> <p>14 if you're going to accuse the authors of the McGovern</p> <p>15 study of scientific fraud?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 <b>A. I -- I was being very careful not to accuse</b></p> <p>19 <b>anybody.</b></p> <p>20 Q. Okay. Then --</p> <p>21 <b>A. I said --</b></p> <p>22 Q. -- accuse them of data manipulation.</p> <p>23 <b>A. I said it raises the concerns of that.</b></p> <p>24 Q. Do you know who Mark Albrecht is, what his</p> <p>25 credentials are?</p>
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<p>1 question, move to strike counsel's preamble, and</p> <p>2 misstates and mischaracterizes the evidence.</p> <p>3 MS. CONLIN: You may answer.</p> <p>4 <b>A. I -- I have no reason to believe that Dr.</b></p> <p>5 <b>Reed was lying.</b></p> <p>6 Q. Okay. And you say, in connection with</p> <p>7 paragraph 29, it suggests the possibility of data</p> <p>8 manipulation.</p> <p>9 <b>A. Uh-huh. Yes.</b></p> <p>10 Q. And again, data manipulation by the authors</p> <p>11 of the McGovern study?</p> <p>12 <b>A. Ultimately, yes.</b></p> <p>13 Q. Okay. So assuming that Dr. Reed was not</p> <p>14 lying under oath when he said the reason why we</p> <p>15 started in July of '08 was because that's when we had</p> <p>16 full reporting, what is the data manipulation that</p> <p>17 you're referencing there?</p> <p>18 MR. GORDON: Object to the form of the</p> <p>19 question, incomplete hypothetical, assumes facts not</p> <p>20 in evidence.</p> <p>21 <b>A. I -- I -- I have seen some earlier work that</b></p> <p>22 <b>I think came from Mr. Albrecht, but I'm not certain,</b></p> <p>23 <b>which suggested a different starting date for the</b></p> <p>24 <b>analysis which comprises the McGovern study, and it</b></p> <p>25 <b>was not July but I think it was the following</b></p>	<p>1 <b>A. I think that he has a master's degree from</b></p> <p>2 <b>the University of Minnesota in statistics.</b></p> <p>3 Q. And he's a professor there?</p> <p>4 <b>A. I didn't know that.</b></p> <p>5 MR. GORDON: Object to the form of the</p> <p>6 question, assumes facts not in evidence.</p> <p>7 Q. Are you -- are you -- are --</p> <p>8 Is it Mark Albrecht who engaged in data</p> <p>9 manipulation? You referenced him.</p> <p>10 <b>A. I don't know.</b></p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question.</p> <p>13 Q. Okay.</p> <p>14 <b>A. I don't know.</b></p> <p>15 Q. All right. Was it Dr. Reed, Dr. --</p> <p>16 How about Dr. Belani?</p> <p>17 MR. GORDON: Same objection.</p> <p>18 <b>A. I don't know.</b></p> <p>19 Q. Okay. But as you sit here, you don't have</p> <p>20 any evidence to refute Dr. Reed's sworn testimony that</p> <p>21 the reason they started in July of '08 was because</p> <p>22 that was the first time they felt like they had full</p> <p>23 implementation of surveillance and reporting of DJIs</p> <p>24 in knees and hips.</p> <p>25 MR. GORDON: Object to the form of the</p>

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<p style="text-align: right;">Page 229</p> <p>1 question.</p> <p>2 <b>A. I -- I earlier said that there were earlier</b></p> <p>3 <b>efforts at the analysis which started on different</b></p> <p>4 <b>dates. The information about when the surveillance</b></p> <p>5 <b>began I assume didn't change over time, and so it</b></p> <p>6 <b>suggests that the analysis was changed over time.</b></p> <p>7 <b>That's all I'm saying.</b></p> <p>8 Q. And -- and can you answer my question now?</p> <p>9 MS. CONLIN: Can you read it back, Mr. Court</p> <p>10 Reporter.</p> <p>11 (Record read by the court reporter.)</p> <p>12 MS. CONLIN: You may answer.</p> <p>13 MR. GORDON: Same objection.</p> <p>14 <b>A. I have no basis to refute his statement, but</b></p> <p>15 <b>I have reason to question it.</b></p> <p>16 Q. Okay. And that's the same individual that</p> <p>17 you relied on repeatedly throughout your expert</p> <p>18 report; correct?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 <b>A. I quoted him a number of times, yes.</b></p> <p>22 Q. Thank you.</p> <p>23 MS. CONLIN: Why don't we take a break here.</p> <p>24 THE REPORTER: Off the record, please.</p> <p>25 (Recess taken.)</p>	<p style="text-align: right;">Page 231</p> <p>1 standard adhesive addressing to a jubilee dressing</p> <p>2 that would statistically significantly alter infection</p> <p>3 rates among arthroplasties?</p> <p>4 <b>A. That was the question that was posed.</b></p> <p>5 Q. Yes.</p> <p>6 <b>A. Yes. And you're asking do I have --</b></p> <p>7 <b>And his answer was "I am not aware of any</b></p> <p>8 <b>such paper."</b></p> <p>9 Q. Are you aware of any?</p> <p>10 <b>A. I have not, in depth, read about the jubilee</b></p> <p>11 <b>dressing.</b></p> <p>12 Q. Okay. If you look on page 409 and at line</p> <p>13 four:</p> <p>14 "Question: Are you aware of any evidence</p> <p>15 that is statistically significant that suggests the</p> <p>16 use of MSSA screening significantly impacts the rate</p> <p>17 of deep joint infections among patients?</p> <p>18 "Answer: I'm not aware of any such papers."</p> <p>19 Do you see that?</p> <p>20 <b>A. I do.</b></p> <p>21 Q. Are you aware of any such papers?</p> <p>22 <b>A. I thought I was. Perhaps I'm not. I had</b></p> <p>23 <b>Dr. Reed's statement which I had referred to, I think,</b></p> <p>24 <b>specifically. I don't remember whether I have one</b></p> <p>25 <b>that specifically addresses joint infection.</b></p>
<p style="text-align: right;">Page 230</p> <p>1 (Exhibit 28 was marked for</p> <p>2 identification.)</p> <p>3 BY MS. CONLIN:</p> <p>4 Q. I've handed you, sir, what's been marked as</p> <p>5 Borak Exhibit 28, which is another excerpt out of day</p> <p>6 two of the deposition of Dr. McGovern. You can take a</p> <p>7 look on the back page of this excerpt exhibit and</p> <p>8 direct your attention down to page 408. At line 17 it</p> <p>9 says:</p> <p>10 "Are you aware of any paper that is</p> <p>11 adequately powered that shows a change from a standard</p> <p>12 adhesive dressing to a jubilee dressing would</p> <p>13 statistically significant -- significantly alter</p> <p>14 infection rates among arthroplasties?" Do you see</p> <p>15 that?</p> <p>16 <b>A. I do.</b></p> <p>17 Q. And he says, "I am not aware of any such</p> <p>18 paper." Do you see that?</p> <p>19 <b>A. I do.</b></p> <p>20 Q. Do you have any reason to dispute that?</p> <p>21 MR. GORDON: To dispute what?</p> <p>22 <b>A. That he said that?</b></p> <p>23 Q. I'll rephrase it.</p> <p>24 Are you aware of any paper that is</p> <p>25 adequately powered that shows a change from the</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Okay. Directing your attention back to your</p> <p>2 report, page 21, did you find -- based on your review</p> <p>3 of the record, did you find consistency among the</p> <p>4 bubble and particle studies as it relates to use of</p> <p>5 the Bair Hugger increasing particulates or bubbles</p> <p>6 over the surgical site?</p> <p>7 <b>A. I thought there was inconsistency, but I did</b></p> <p>8 <b>not do a systematic review and I did not offer an</b></p> <p>9 <b>opinion on that.</b></p> <p>10 Q. Okay. So you don't know.</p> <p>11 We looked at, for example, the corporate</p> <p>12 representative Al Van Duren's testimony this morning</p> <p>13 that said that every single study out there shows an</p> <p>14 increase in absolute numbers of particles when Bair</p> <p>15 Hugger is in use. You don't have any reason to</p> <p>16 dispute that; do you?</p> <p>17 <b>A. I -- I have read other papers, I think</b></p> <p>18 <b>there's one by somebody named Oguz, who found no</b></p> <p>19 <b>evidence of increase. I -- I'm --</b></p> <p>20 <b>But it's not an area that I have</b></p> <p>21 <b>particularly taken on for myself, and I don't have</b></p> <p>22 <b>expertise in that area.</b></p> <p>23 Q. Okay. So you don't have any reason to</p> <p>24 dispute at least Al Van Duren's testimony as a</p> <p>25 corporate representative for 3M.</p>

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<p style="text-align: right;">Page 233</p> <p>1       <b>A. I would have no basis to dispute the</b>  2       <b>corporate representative's opinion.</b>  3       Q. Now I'd like to direct your attention to --  4       You understand that each of the authors of  5       the McGovern study continue to stand behind the  6       conclusions in that study; right, sir?  7       MR. GORDON: Object to the form of the  8       question.  9       <b>A. I'm not sure which conclusions. What?</b>  10      Q. That the study is valid and that there's a  11      significant increased risk of a deep joint infection  12      by use of the Bair Hugger.  13      MR. GORDON: Object to the form of the  14      question and mis --  15      <b>A. I think each of them --</b>  16      MR. GORDON: Let me finish my objection.  17      THE WITNESS: Sorry.  18      MR. GORDON: -- assumes facts not in  19      evidence, mischaracterizes the evidence.  20      MS. CONLIN: You may answer.  21      <b>A. I believe each of the authors has said that</b>  22      <b>this shows an association, not a causation, so it</b>  23      <b>agreed with what you just said in your question.</b>  24      Q. Okay. You would agree that each of the  25      authors, when questioned under oath, stand by the</p>	<p style="text-align: right;">Page 235</p> <p>1       Q. Okay. But they --  2       Even those who said there might have been  3       one more infection said there would still be a  4       significant odds risk ratio; correct?  5       <b>A. I don't think --</b>  6       MR. GORDON: Same objections.  7       Q. Well let me ask it a different way.  8       Did you see any of them in their depositions  9       under oath say that the findings that they reached in  10      McGovern that use of the Bair Hugger is associated  11      with an increased risk of deep joint infection was  12      wrong?  13      <b>A. I saw some of them say that the numbers</b>  14      <b>included in the publications --</b>  15      Q. I'm not asking about that.  16      <b>A. -- were wrong.</b>  17      Q. I'm asking about the conclusions in the  18      paper. Can you answer my question?  19      <b>A. Well, but if the conclusion is, as you</b>  20      <b>suggested before, an odds ratio of 3.8 --</b>  21      Q. That's not what I asked.  22      MS. CONLIN: Mr. Stirewalt, can you read it  23      back, please.  24      (Record read by the court reporter.)  25      <b>A. I did not see any of them withdraw the</b></p>
<p style="text-align: right;">Page 234</p> <p>1       veracity and the validity of the findings as expressed  2       in the McGovern paper; correct?  3       <b>A. I think that they indicated that the numbers</b>  4       <b>were not correct. Now when you say "veracity and</b>  5       <b>validity," I'm not sure how to deal with that if the</b>  6       <b>numbers are not correct.</b>  7       Q. Okay. Let me state it a different way  8       because I don't want to drag you through all the  9       transcripts.  10      You'd agree with me that each of the authors  11      testified under oath that they stand by the  12      conclusions in the McGovern paper that they found a  13      3.8 increased risk of infection when the Bair Hugger  14      was used over the Hot Dog; correct?  15      <b>A. My impress --</b>  16      MR. GORDON: Object to form -- object to --  17      Well same objections as the last one.  18      <b>A. Just for the record, I apologize to</b>  19      <b>everybody for stepping on you. It's late in the day</b>  20      <b>and I'm losing my control.</b>  21      My understanding was that one or more of the  22      authors agreed that the numbers were not correct, and  23      if the numbers were changed according to what was  24      talked about in the depositions, then the 3.8 number  25      would not be correct. That's my understanding.</p>	<p style="text-align: right;">Page 236</p> <p>1       <b>conclusion in the paper.</b>  2       MS. CONLIN: Thank you. Mark this, please.  3       (Exhibit 29 was marked for  4       identification.)  5       BY MS. CONLIN:  6       Q. I've handed you what's been marked as  7       Deposition Exhibit 29, Borak Deposition Exhibit 29 --  8       MR. GORDON: Is that 29 or 30? Oh, you used  9       a premarked. I'm sorry. Go ahead.  10      Doesn't this deal with Nachtsheim?  11      MS. CONLIN: Yeah.  12      Q. Let me start over again.  13      You've been handed, sir, what's been marked  14      as Borak Deposition Exhibit 29, which is an excerpt  15      out of the Professor Nachtsheim deposition, one of  16      the depositions that you relied on; correct?  17      <b>A. Yes.</b>  18      Q. Do you know whether Professor --  19      Do you have any reason to dispute the  20      honesty and scientific credibility of Professor  21      Nachtsheim?  22      <b>A. I have no particular reason to do that.</b>  23      Q. Okay. And if you look at internal page 350  24      of this exhibit --  25      Do you have it there?</p>

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<p>1 <b>A. I see it.</b></p> <p>2 Q. -- the question is:</p> <p>3 "Question: And do you -- And you continue</p> <p>4 to stand by the results of the observational</p> <p>5 studies --</p> <p>6 "Yes.</p> <p>7 -- "in the McGovern publication?</p> <p>8 "I do."</p> <p>9 Do you see that?</p> <p>10 <b>A. I do see that.</b></p> <p>11 Q. Okay. Do you have any reason to suspect</p> <p>12 that Professor Nachtsheim engaged in data</p> <p>13 manipulation?</p> <p>14 <b>A. I have no reason to suggest that he did</b></p> <p>15 <b>that.</b></p> <p>16 Q. Okay. And have you seen anything that would</p> <p>17 suggest that Professor Nachtsheim would allow</p> <p>18 somebody to manipulate data in connection with a study</p> <p>19 that he was on?</p> <p>20 <b>A. I -- I have no ability to comment on that.</b></p> <p>21 Q. Finally, if we can look, sir, at your</p> <p>22 summary, which is contained on page 22.</p> <p>23 <b>A. Yes.</b></p> <p>24 Q. And you've got a summary, "Following is a</p> <p>25 list of my opinions, all to a reasonable degree of</p>	<p>1 Augustine publication or both are scientifically</p> <p>2 valid, then your opinion as expressed in 74e of your</p> <p>3 report also wouldn't hold up; correct?</p> <p>4 <b>A. If --</b></p> <p>5 <b>Yes.</b></p> <p>6 Q. Okay. And same with respect to your final</p> <p>7 conclusion, 74f, "Because there is insufficient</p> <p>8 evidence that there's a significant association</p> <p>9 between the Bair Hugger and deep joint infections,</p> <p>10 Bair Hugger does not represent a substantial</p> <p>11 contributing cause of deep joint infections."</p> <p>12 Correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 MS. CONLIN: Okay. Let me check my notes.</p> <p>15 I think we're done.</p> <p>16 THE REPORTER: Off the record, please.</p> <p>17 (Recess taken.)</p> <p>18 (Exhibit 30 was marked for</p> <p>19 identification.)</p> <p>20 BY MS. CONLIN:</p> <p>21 Q. I've handed you, sir, what's been --</p> <p>22 <b>A. Can I first --</b></p> <p>23 <b>Yes. Please go ahead. I'm sorry.</b></p> <p>24 Q. -- what's been marked as Borak Exhibit 30,</p> <p>25 which is the Bradford-Hill article entitled "The</p>
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<p>1 medical and scientific certainty." Do you see that?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. Okay. You'd agree with me that each of your</p> <p>4 conclusions stated there rely on a finding that the</p> <p>5 McGovern study is not valid; correct?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question.</p> <p>8 <b>A. Not valid or wrong. Perhaps that's the same</b></p> <p>9 <b>thing.</b></p> <p>10 Q. Okay. But you'd agree with me if -- if the</p> <p>11 McGovern paper is legitimate, if the findings in there</p> <p>12 are correct, then none of your opinions as expressed</p> <p>13 in your summary have merit; correct?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 <b>A. The first four are probably -- a through d</b></p> <p>17 <b>probably follow from the point that you've just made.</b></p> <p>18 <b>The issue is whether the McGovern paper is or is not a</b></p> <p>19 <b>legitimate basis of evidence.</b></p> <p>20 Q. Well e relies -- your conclusion in e also</p> <p>21 require -- relies on McGovern being invalid; correct?</p> <p>22 <b>A. No, no, it's also on the current Augustine</b></p> <p>23 <b>being invalid.</b></p> <p>24 Q. Okay. Fair enough. But your -- okay.</p> <p>25 So 74e, if either McGovern or the new</p>	<p>1 Environment and Disease: Association or Causation?"</p> <p>2 Correct?</p> <p>3 <b>A. Correct.</b></p> <p>4 Q. And you've actually cited this publication</p> <p>5 in connection with your work; correct?</p> <p>6 <b>A. Correct.</b></p> <p>7 Q. I'd like to direct your attention to the</p> <p>8 last page, page 12.</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. Second-to-last paragraph, "All scientific</p> <p>11 work is incomplete -- whether it be observational or</p> <p>12 experimental. All scientific work is liable to be</p> <p>13 upset or modified by advancing knowledge. That does</p> <p>14 not confer upon us a freedom to ignore the knowledge</p> <p>15 we already have, or to postpone the action that it</p> <p>16 appears to demand at a given time." Do you see that?</p> <p>17 <b>A. I do.</b></p> <p>18 Q. Do you agree with that statement?</p> <p>19 <b>A. I think it's very reasonable.</b></p> <p>20 MS. CONLIN: Okay. No further questions.</p> <p>21 THE REPORTER: Let's go off the record a</p> <p>22 moment, please.</p> <p>23 REDIRECT EXAMINATION</p> <p>24 BY MR. GORDON:</p> <p>25 Q. Dr. Borak, if I could ask you to just pull</p>

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<p>1 out Exhibit 27.</p> <p>2 MS. CONLIN: Which exhibit is that, Mr.</p> <p>3 Gordon?</p> <p>4 MR. GORDON: It is a piece of testimony from</p> <p>5 the first day of Dr. McGovern.</p> <p>6 A. Yes, sir.</p> <p>7 Q. And if you want to turn to page 115,</p> <p>8 transcript page 115.</p> <p>9 A. Yes, sir.</p> <p>10 Q. And that -- the first question and answer</p> <p>11 that -- the question and answer that Ms. Conlin asked</p> <p>12 you about.</p> <p>13 A. "...do you believe it would have been</p> <p>14 reasonable" --</p> <p>15 Yes, I see that.</p> <p>16 Q. Okay. And you said you also read the --</p> <p>17 You were reading to yourself the -- the</p> <p>18 second question. Could you read that -- the question</p> <p>19 and answer that you read to yourself.</p> <p>20 A. The paragraph that starts "We -- if we have</p> <p>21 said that we believe, or think" --</p> <p>22 Q. Yeah. In fact, you know what? For context,</p> <p>23 would you mind just reading both questions and</p> <p>24 answers, the one that Ms. Conlin asked you and then</p> <p>25 the -- then the next one.</p>	<p>1 benefit to using one particular agent/regimen."</p> <p>2 A. Yes.</p> <p>3 Q. Do you see that?</p> <p>4 Okay. And on the same page does it discuss</p> <p>5 specifically the regimen of Gentamicin only?</p> <p>6 A. It reads, "There is no evidence for the use</p> <p>7 of systematic -- systemic gentamicin as prophylaxis in</p> <p>8 primary elective total hip arthroplasty and total knee</p> <p>9 arthroplasty surgery."</p> <p>10 Q. Okay. And do you have any reason to</p> <p>11 disagree with Dr. Reed's conclusion that there was no</p> <p>12 evidence for the use of system -- systemic Gentamicin</p> <p>13 as prophylaxis in primary elective THA and TKA</p> <p>14 surgery?</p> <p>15 A. I -- I have no reason to disagree.</p> <p>16 Q. And what was the antibiotic prophylaxis that</p> <p>17 was being used at the beginning of the Bair Hugger-</p> <p>18 only period?</p> <p>19 A. Gentamicin only.</p> <p>20 Q. Okay. And does it say anything about the</p> <p>21 Teicoplanin?</p> <p>22 A. It reads, "Four randomised controlled trials</p> <p>23 provide strong evidence for the use of a single dose</p> <p>24 of 400 milligrams of teicoplanin at induction.</p> <p>25 Although there is no evidence to suggest that higher</p>
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<p>1 A. The question is:</p> <p>2 "Based on the evidence that you had, do you</p> <p>3 believe it would have been reasonable for your paper</p> <p>4 to imply a causal connection?</p> <p>5 "Answer: If properly qualified, yes.</p> <p>6 "Question: What would the proper</p> <p>7 qualifications be?</p> <p>8 "Answer: We -- if we had said that we</p> <p>9 believe, or think, that there is evidence that</p> <p>10 suggests that forced-air warming has an influence on</p> <p>11 infection, but that we recognize there are confounding</p> <p>12 factors, then that implication is tempered with the</p> <p>13 recognition that there are other effects that could be</p> <p>14 at play."</p> <p>15 Q. Okay. You can put that -- thank you, you</p> <p>16 can put that aside.</p> <p>17 And then I just want to pull -- have you</p> <p>18 pull out Exhibit 22, I think, the Hickson paper, and I</p> <p>19 will direct you to the same page Ms. Conlin read from,</p> <p>20 page 186, in that second full paragraph there which</p> <p>21 is -- that's -- that's the one she read from where</p> <p>22 she -- where it said -- where this paper -- Dr. Reed</p> <p>23 is one of the authors, "Although there is a large body</p> <p>24 of evidence for the use of prophylactic antibiotics in</p> <p>25 primary hip and knee arthroplasty, there is no clear</p>	<p>1 doses or prolonged courses of treatment result in</p> <p>2 fewer SSIs, studies have shown that this dose may be</p> <p>3 inadequate for patients weighing over 70 kilograms."</p> <p>4 Q. Okay. Do you have any disagree -- reason to</p> <p>5 disagree with Dr. Reed's statements about the efficacy</p> <p>6 of Teicoplanin?</p> <p>7 A. I have no reason to disagree with that.</p> <p>8 Q. And what was the antibiotic that was added</p> <p>9 to the prophylactic antibiotic regimen prior to the</p> <p>10 switchover to the Hot Dog in the McGovern paper?</p> <p>11 A. Teicoplanin was added to a reduced</p> <p>12 Gentamicin dose.</p> <p>13 Q. Okay. Do you recall any discussion in Mr.</p> <p>14 Albrecht's testimony about the statistical comparison</p> <p>15 between a time period during the Bair Hugger-only</p> <p>16 cohort where the same antibiotics and same</p> <p>17 thromboprophylaxis was used as was used in the Hot Dog</p> <p>18 period?</p> <p>19 A. I recall that there was such a discussion.</p> <p>20 Q. And do you recall whether -- what -- what</p> <p>21 Mr. Albrecht had to say about what -- about whether</p> <p>22 there was or was not any statistically significant</p> <p>23 difference in the infection rate in -- in those two</p> <p>24 periods?</p> <p>25 MS. CONLIN: Objection, misstates the record</p>

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<p>1 and assumes facts not in evidence.</p> <p>2 <b>A. I -- I believe he reported that there was no</b></p> <p>3 <b>significant difference.</b></p> <p>4 Q. And did you read any testimony from Dr. Reed</p> <p>5 about that same comparison; in other words, the -- the</p> <p>6 period during the Bair Hugger-only cohort when it was</p> <p>7 the same antibiotics and same thromboprophylaxis as</p> <p>8 the Hot Dog period?</p> <p>9 <b>A. I think I do remember it.</b></p> <p>10 Q. Do you recall what Dr. Reed testified</p> <p>11 about --</p> <p>12 <b>A. I'm sorry.</b></p> <p>13 Q. -- in that comparison?</p> <p>14 <b>A. I -- I -- I, by now, cannot distinguish</b></p> <p>15 <b>between the two, al -- but I -- I --</b></p> <p>16 <b>I don't remember specifically. I'm sorry.</b></p> <p>17 Q. By -- by "the two," do you mean Reed and</p> <p>18 Albrecht or Reed and McGovern?</p> <p>19 <b>A. Yes, Reed and McGovern.</b></p> <p>20 MR. GORDON: Okay. No further question.</p> <p>21 MS. CONLIN: One followup.</p> <p>22 RE-CROSS EXAMINATION</p> <p>23 BY MS. CONLIN:</p> <p>24 Q. With respect to the Hickson study and the</p> <p>25 statements from that study that you just read, those</p>	<p>1 antibiotics in primary hip and knee arthroplasty,</p> <p>2 there is no clear benefit to using one particular</p> <p>3 agent/regimen."</p> <p>4 Could you read the next sentence in that</p> <p>5 paragraph.</p> <p>6 <b>A. "This is unsurprising, given that prosthetic</b></p> <p>7 <b>joint infection is a rare event and that a randomised</b></p> <p>8 <b>study would need over 3000 patients per group in order</b></p> <p>9 <b>to demonstrate a reduction in the rate of infection</b></p> <p>10 <b>from 2 percent to 1 percent, with a power of 90</b></p> <p>11 <b>percent at the 95 percent confidence interval."</b></p> <p>12 Q. Do you know what "PJI" refers to there?</p> <p>13 <b>A. Prosthetic joint infection.</b></p> <p>14 Q. Okay.</p> <p>15 <b>A. That would lead me to correct my response</b></p> <p>16 <b>earlier. This suggests that this was specifically</b></p> <p>17 <b>concerned with prosthetic joint infections.</b></p> <p>18 MR. GORDON: Thank you. Nothing further.</p> <p>19 RE-RE-CROSS EXAMINATION</p> <p>20 BY MS. CONLIN:</p> <p>21 Q. Can you go back to the language that Mr.</p> <p>22 Gordon quoted you during his first examination of you</p> <p>23 and read that back into the record.</p> <p>24 <b>A. Are you speaking to me?</b></p> <p>25 Q. Yes.</p>
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<p>1 were for SSIs, not necessarily deep joint infections;</p> <p>2 correct?</p> <p>3 MR. GORDON: Object to the form of the</p> <p>4 question. Ask you to read the -- the whole paper if</p> <p>5 she -- if you want to go there.</p> <p>6 MS. CONLIN: No. I'm asking him with</p> <p>7 respect to the specific statement that you just had</p> <p>8 him read into the record.</p> <p>9 Q. It was directed to SSIs and not specifically</p> <p>10 deep joint infections; correct?</p> <p>11 <b>A. It was specifically hip and knee</b></p> <p>12 <b>arthroplasty, but I do not see a distinction of joint</b></p> <p>13 <b>versus other infections.</b></p> <p>14 Q. Right. And the language that Mr. Gordon</p> <p>15 just had you read related to SSIs; correct?</p> <p>16 <b>A. Yes, I think so.</b></p> <p>17 MS. CONLIN: No further questions.</p> <p>18 RE-REDIRECT EXAMINATION</p> <p>19 BY MR. GORDON:</p> <p>20 Q. Unfortunately, we're going to have to go</p> <p>21 back to the Hickson paper then, Exhibit 22. Go</p> <p>22 back -- go back to page 186 and the statement that --</p> <p>23 We'll go back to the original statement that</p> <p>24 Ms. Conlin read from that. "Although there is a large</p> <p>25 body of evidence for the use of prophylactic</p>	<p>1 <b>A. You want me to go back to what?</b></p> <p>2 Q. Read the statement that Mr. Gordon read you</p> <p>3 out of the Hickson paper.</p> <p>4 <b>A. Out of the Hickson paper.</b></p> <p>5 Q. Yes, prior to the time he just showed you</p> <p>6 that one.</p> <p>7 <b>A. I -- I'm getting confused and it's late.</b></p> <p>8 <b>Would you point to which paragraph you would like me</b></p> <p>9 <b>to look at.</b></p> <p>10 MS. CONLIN: Which page and paragraph was</p> <p>11 it, Mr. Gordon?</p> <p>12 MR. GORDON: One fif --</p> <p>13 One eighty-six, second full paragraph.</p> <p>14 MS. CONLIN: No, the first time you went</p> <p>15 over it with him.</p> <p>16 MR. GORDON: Oh, earlier?</p> <p>17 MS. CONLIN: Yes. That was early --</p> <p>18 MR. GORDON: Same page, same page, and it</p> <p>19 was on the other side of the -- there was --</p> <p>20 <b>A. Oh, the Gentamicin and the Teicoplanin</b></p> <p>21 <b>questions?</b></p> <p>22 Q. Yes.</p> <p>23 <b>A. And what is the question you would like me</b></p> <p>24 <b>to respond to?</b></p> <p>25 Q. You know what? Let's just let the record</p>

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<p style="text-align: right;">Page 249</p> <p>1 speak for itself. We'll be done.  2 MS. CONLIN: I have no further questions.  3 THE REPORTER: Off the record, please.  4 (Deposition concluded.)  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 251</p> <p>1 CERTIFICATE  2 I, JONATHAN BORAK, hereby certify that I  3 have carefully read the foregoing transcript, and that  4 the same is a true and complete, full and correct  5 transcription of my deposition, except:  6 PAGE/LINE CHANGE REASON  7  8  9  10  11  12  13  14  15  16  17 JONATHAN BORAK  18 Deponent  19  20 Signed and sworn to before me this ____ day of  21 August, 2017.  22  23 _____  24 Notary Public  25</p>
<p style="text-align: right;">Page 250</p> <p>1 CERTIFICATE  2 I, Richard G. Stirewalt, hereby certify that  3 I am qualified as a verbatim shorthand reporter, that  4 I took in stenographic shorthand the deposition of  5 JONATHAN BORAK at the time and place aforesaid, and  6 that the foregoing transcript is a true and correct,  7 full and complete transcription of said shorthand  8 notes, to the best of my ability.  9 Dated at Deerwood, Minnesota, this 26th day  10 of July, 2017.  11  12  13  14  15  16  17 RICHARD G. STIREWALT  18 Registered Professional Reporter  19 Notary Public  20  21  22  23  24  25</p>	

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